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MARS 2022

ÉTAT DES CONNAISSANCES

# Intensification posologique des agents biologiques - Gastroentérologie, rhumatologie et dermatologie

## Annexes complémentaires

Une production de l'Institut national d'excellence en santé et en services sociaux (INESSS)

Direction de l'évaluation des médicaments et des technologies à des fins de remboursement

Québec

Le présent document contient les annexes complémentaires à l'état des connaissances *Intensification posologique des agents biologiques*.

Le contenu de cette publication a été rédigé et édité par l'INESSS.

Ces annexes et le rapport final sont accessibles en ligne dans la section *Publications* de notre site *Web*.

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**Responsabilité**

L'Institut rend accessibles les principales informations qui ont servi à la préparation du rapport *Intensification posologique des agents biologiques* aux lecteurs qui désirent plus de détails sur sa démarche scientifique.

Ce document n'a pas fait l'objet d'une révision linguistique. Il ne reflète pas forcément les opinions des autres personnes consultées aux fins du présent dossier.

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# ANNEXE A

## Stratégies de repérage de l'information scientifique

### Bases de données bibliographiques

| **MEDLINE (Ovid)**<br>**Date du repérage : juin 2021**<br>**Limites : 2000- (ligne 35 : 2016-) ; anglais, français** | |
|---|---|
| 1 | exp *Inflammatory Bowel Diseases/dt |
| 2 | (colitis gravis OR crohn disease OR crohns disease OR crohn's disease OR crohn's enteritis OR enteritis regionalis OR granulomatous colitis OR granulomatous enteritis OR ibd OR idiopathic proctocolitis OR ileocolitis OR inflammatory bowel disease* OR morbus crohn OR regional enteritis OR regional enterocolitis OR regional ileitis OR terminal ileitis OR ulcerative colitis).ti,ab |
| 3 | 1 OR 2 |
| 4 | exp *Arthritis, Rheumatoid/dt |
| 5 | (adult-onset still's disease OR adult onset still disease OR arthritis deformans OR arthrosis deformans OR beauvais disease OR caplan syndrome OR chronic articular rheumatism OR felty syndrome OR inflammatory arthritis OR rheumarthritis OR rheumatic arthritis OR rheumatic polyarthritis OR rheumatoid arthritis OR rheumatoid nodule OR rheumatoid vasculitis OR sjogren's syndrome).ti,ab |
| 6 | 4 OR 5 |
| 7 | *Arthritis, Juvenile/dt |
| 8 | ((juvenile ADJ3 (arthritis OR chronic arthritis OR enthesitis-related arthritis OR idiopathic arthritis OR oligoarthritis OR onset still disease OR onset stills disease OR onset still's disease OR polyarthritis OR psoriatic arthritis OR rheumatoid arthritis OR rheumatoid polyarthritis OR systemic arthritis)) OR arthritis deformans juvenilis OR chronic juvenile arthritis OR juvenile arthropathy).ti,ab |
| 9 | 7 OR 8 |
| 10 | *Arthritis, Psoriatic/dt |
| 11 | (((psoriasis OR psoriatic*) ADJ1 (arthritic OR arthritis OR arthropathic* OR arthropath* OR polyarthritis OR rheumatism OR rheumatoid arthritis)) OR alibert bazin disease).ti,ab |
| 12 | 10 OR 11 |
| 13 | *Spondylitis, Ankylosing/dt |
| 14 | (ankylating spondylitis OR ankylopoietic spondyl* ORankylosing spine OR ankylosing spondilitis OR ankylosing spondyl* OR ankylosis spondylitis OR ankylotic spondylitis OR bechterew disease OR bechterews disease OR bechterew's disease OR bekhterev disease OR marie-struempell disease OR morbus bechterew OR rheumatoid spondylitis OR spinal ankylosis OR spine ankylosis OR spondylarthritis ankylopoietica OR spondylarthritis ankylosans OR spondylarthrosis ankylopoietica OR spondylitis ankylopoietica OR spondyloarthritis ankylopoietica OR vertebral ankylosis).ti,ab |
| 15 | 13 OR 14 |
| 16 | exp *Psoriasis/dt |
| 17 | (psorias* OR psoriatic*).ti,ab |
| 18 | 16 OR 17 |
| 19 | 3 OR 6 OR 9 OR 12 OR 15 OR 18 |
| 20 | exp *Biological Products/ad,tu |
| 21 | (anti-tnf* OR (tnf* ADJ3 (antagonist* OR block* OR inhibitor*)) OR (anti ADJ (il-17 OR interleukin-17 OR il-17a OR interleukin-17a OR il-12 OR interleukin-12 OR il-23 OR interleukin-23 OR il-6 OR interleukin-6)) OR (anti ADJ (cd80 OR cd86 OR (itga4 AND itgb7) OR cd20)) OR ((il-17 OR interleukin-17 OR il-17a OR interleukin-17a OR il-12 OR interleukin-12 OR il-23 OR interleukin-23 OR il-6 OR interleukin-6 OR cd80 OR cd86 OR itga4 OR itgb7 OR cd20) ADJ3 (antagonist* OR block* OR inhibitor*))).ti,ab |

| | |
|---|---|
| 22 | (biologic agent* OR biologic drug* OR biologic medicine* OR biologic pharmaceutic* OR biologic product* OR biologic therap* OR biologic treatment* OR biological drug* OR biological medicine* OR biological product* OR biological therap* OR biological treatment* OR biologicals OR biologics OR biomedicament* OR biomedicine* OR bio-medicine* OR biopharmaceutic* OR bio-pharmaceutic* OR biosimilar* OR bio-similar* OR biotherap* OR bio-therap* OR originator* OR reference biologic* OR reference product*).ti,ab |
| 23 | 20 OR 21 OR 22 |
| 24 | exp *Antibodies, Monoclonal/ad,tu |
| 25 | (abatacept OR actemra OR adalimumab OR amjevita OR atlizumab OR belatacept OR brodalumab OR certolizumab pegol OR cimzia OR cosentyx OR cyltezo OR enbrel OR entyvio OR erelzi OR etanercept OR golimumab OR guselkumab OR humira OR inflectra OR infliximab OR ixekizumab OR kevzara OR mabthera OR monoclonal antibod* OR nulojix OR orencia OR remicade OR renflexis OR rituxan OR rituximab OR risankizumab OR roactemra OR sarilumab OR secukinumab OR siliq OR simponi OR skyrizi OR stelara OR taltz OR tocilizumab OR tremfya OR ustekinumab OR vedolizumab).ti |
| 26 | (abatacept OR actemra OR adalimumab OR amjevita OR atlizumab OR belatacept OR brodalumab OR certolizumab pegol OR cimzia OR cosentyx OR cyltezo OR enbrel OR entyvio OR erelzi OR etanercept OR golimumab OR guselkumab OR humira OR inflectra OR infliximab OR ixekizumab OR kevzara OR mabthera OR monoclonal antibod* OR nulojix OR orencia OR remicade OR renflexis OR rituxan OR rituximab OR risankizumab OR roactemra OR sarilumab OR secukinumab OR siliq OR simponi OR skyrizi OR stelara OR taltz OR tocilizumab OR tremfya OR ustekinumab OR vedolizumab).ti,ab |
| 27 | exp Guidelines as Topic/ OR exp Guideline/ OR Health Planning Guidelines/ OR exp Consensus/ OR exp Consensus Development Conference/ OR exp Consensus Development Conferences as Topic/ OR exp Critical Pathways/ OR Clinical Conference.pt OR exp Algorithms/ OR exp Clinical Protocols/ OR (guideline* OR guide line* OR cpg or cpgs OR guidance OR practical guide* OR (best ADJ3 practice*) OR (evidence ADJ2 (base* OR report* OR synthes* OR research OR practice* OR best)) OR consensus OR algorithm* OR (clinical ADJ2 (path OR paths OR pathway* OR protocol*)) OR ((critical OR clinical) ADJ2 (path OR paths OR pathway*)) OR recommendation* OR committee opinion* OR policy statement* OR position statement* OR practice parameter* OR practice pathway* OR practice protocol* OR ((standard OR standards) ADJ2 (care* OR practice*)) OR (gold ADJ2 standard*)).ti,bt |
| 28 | (dosage* OR dose* OR dosing OR drug OR drugs OR manag* OR medication* OR pharmaceutic* OR pharmaco* OR therap* OR treat*).ti |
| 29 | 19 AND 27 |
| 30 | 29 AND (23 OR 24 OR 26 OR 28) |
| 31 | Meta-Analysis.pt OR exp Meta-Analysis as Topic/ OR Systematic Review/ OR exp Technology Assessment, Biomedical/ OR (meta-analy* OR metaanaly* OR met analy* OR metanaly* OR meta-review* OR metareview* OR meta regression* OR metaregression* OR meta synthesis OR metasynthesis OR overview of review* OR overviews of reviews OR (systematic* ADJ3 (review* OR overview* OR literature OR search* OR research*)) OR ((quantitative OR methodologic* OR integrativ*) ADJ (review* OR overview* OR synthes*)) OR umbrella review* OR hta or htas OR technology assessment* OR technology overview* OR technology appraisal* OR technology reassessment*).ti,ab,kw OR (review.mp AND ((medline OR pubmed) AND (cochrane OR embase)).ti,ab,kw) |
| 32 | 19 AND 31 |
| 33 | 32 AND (23 OR 24 OR 26) |
| 34 | 30 OR 33 |
| 35 | limit 34 to yr="2016 - 2021" |
| 36 | (cmin OR dosage* OR dose* OR dosing OR escalation OR induction* OR intensification OR monitor* OR tdm).ti,ab |
| 37 | 19 AND 36 |
| 38 | 37 AND (24 OR 25) |
| 39 | limit 38 to yr="2000 - 2021" |
| 40 | 35 OR 39 |
| 41 | Case Reports/ OR Comment/ OR Editorial/ OR Letter/ OR (case report* OR case stud* OR case series OR comment* OR reply OR replies OR editorial* OR letter*).ti |
| 42 | 40 NOT 41 |
| 43 | Animals/ NOT (Humans/ AND Animals/) |
| 44 | 42 NOT 43 |

| Embase (Ovid)<br>Date du repérage : juin 2021<br>Limites : 2000- (ligne 35 : 2016-) ; anglais, français | |
|---|---|
| 1 | exp *Inflammatory Bowel Disease/dt |
| 2 | (colitis gravis OR crohn disease OR crohns disease OR crohn's disease OR crohn's enteritis OR enteritis regionalis OR granulomatous colitis OR granulomatous enteritis OR ibd OR idiopathic proctocolitis OR ileocolitis OR inflammatory bowel disease* OR morbus crohn OR regional enteritis OR regional enterocolitis OR regional ileitis OR terminal ileitis OR ulcerative colitis).ti,ab |
| 3 | 1 OR 2 |
| 4 | exp *Rheumatoid Arthritis/dt |
| 5 | (adult-onset still's disease OR adult onset still disease OR arthritis deformans OR arthrosis deformans OR beauvais disease OR caplan syndrome OR chronic articular rheumatism OR felty syndrome OR inflammatory arthritis OR rheumarthritis OR rheumatic arthritis OR rheumatic polyarthritis OR rheumatoid arthritis OR rheumatoid nodule OR rheumatoid vasculitis OR sjogren's syndrome).ti,ab |
| 6 | 4 OR 5 |
| 7 | exp *Juvenile Rheumatoid Arthritis/dt |
| 8 | ((juvenile ADJ3 (arthritis OR chronic arthritis OR enthesitis-related arthritis OR idiopathic arthritis OR oligoarthritis OR onset still disease OR onset stills disease OR onset still's disease OR polyarthritis OR psoriatic arthritis OR rheumatoid arthritis OR rheumatoid polyarthritis OR systemic arthritis)) OR arthritis deformans juvenilis OR chronic juvenile arthritis OR juvenile arthropathy).ti,ab |
| 9 | 7 OR 8 |
| 10 | *Psoriatic Arthritis/dt |
| 11 | (((psoriasis OR psoriatic*) ADJ1 (arthritic OR arthritis OR arthropathic* OR arthropath* OR polyarthritis OR rheumatism OR rheumatoid arthritis)) OR alibert bazin disease).ti,ab |
| 12 | 10 OR 11 |
| 13 | *Ankylosing Spondylitis/dt |
| 14 | (ankylating spondylitis OR ankylopoietic spondyl* ORankylosing spine OR ankylosing spondilitis OR ankylosing spondyl* OR ankylosis spondylitis OR ankylotic spondylitis OR bechterew disease OR bechterews disease OR bechterew's disease OR bekhterev disease OR marie-struempell disease OR morbus bechterew OR rheumatoid spondylitis OR spinal ankylosis OR spine ankylosis OR spondylarthritis ankylopoietica OR spondylarthritis ankylosans OR spondylarthrosis ankylopoietica OR spondylitis ankylopoietica OR spondyloarthritis ankylopoietica OR vertebral ankylosis).ti,ab |
| 15 | 13 OR 14 |
| 16 | exp *Psoriasis/dt |
| 17 | (psorias* OR psoriatic*).ti,ab |
| 18 | 16 OR 17 |
| 19 | 3 OR 6 OR 9 OR 12 OR 15 OR 18 |
| 20 | exp *Biological Product/ |
| 21 | (anti-tnf* OR (tnf* ADJ3 (antagonist* OR block* OR inhibitor*)) OR (anti ADJ (il-17 OR interleukin-17 OR il-17a OR interleukin-17a OR il-12 OR interleukin-12 OR il-23 OR interleukin-23 OR il-6 OR interleukin-6)) OR (anti ADJ (cd80 OR cd86 OR (itga4 AND itgb7) OR cd20)) OR ((il-17 OR interleukin-17 OR il-17a OR interleukin-17a OR il-12 OR interleukin-12 OR il-23 OR interleukin-23 OR il-6 OR interleukin-6 OR cd80 OR cd86 OR itga4 OR itgb7 OR cd20) ADJ3 (antagonist* OR block* OR inhibitor*))).ti,ab |
| 22 | (biologic agent* OR biologic drug* OR biologic medicine* OR biologic pharmaceutic* OR biologic product* OR biologic therap* OR biologic treatment* OR biological drug* OR biological medicine* OR biological product* OR biological therap* OR biological treatment* OR biologicals OR biologics OR biomedicament* OR biomedicine* OR bio-medicine* OR biopharmaceutic* OR bio-pharmaceutic* OR biosimilar* OR bio-similar* OR biotherap* OR bio-therap* OR originator* OR reference biologic* OR reference product*).ti,ab |
| 23 | 20 OR 21 OR 22 |
| 24 | exp *Monoclonal Antibody/ |

| | |
|---|---|
| 25 | (abatacept OR actemra OR adalimumab OR amjevita OR atlizumab OR belatacept OR brodalumab OR certolizumab pegol OR cimzia OR cosentyx OR cyltezo OR enbrel OR entyvio OR erelzi OR etanercept OR golimumab OR guselkumab OR humira OR inflectra OR infliximab OR ixekizumab OR kevzara OR mabthera OR monoclonal antibod* OR nulojix OR orencia OR remicade OR renflexis OR rituxan OR rituximab OR risankizumab OR roactemra OR sarilumab OR secukinumab OR siliq OR simponi OR skyrizi OR stelara OR taltz OR tocilizumab OR tremfya OR ustekinumab OR vedolizumab).ti |
| 26 | (abatacept OR actemra OR adalimumab OR amjevita OR atlizumab OR belatacept OR brodalumab OR certolizumab pegol OR cimzia OR cosentyx OR cyltezo OR enbrel OR entyvio OR erelzi OR etanercept OR golimumab OR guselkumab OR humira OR inflectra OR infliximab OR ixekizumab OR kevzara OR mabthera OR monoclonal antibod* OR nulojix OR orencia OR remicade OR renflexis OR rituxan OR rituximab OR risankizumab OR roactemra OR sarilumab OR secukinumab OR siliq OR simponi OR skyrizi OR stelara OR taltz OR tocilizumab OR tremfya OR ustekinumab OR vedolizumab).ti,ab |
| 27 | *Algorithm/ OR *Clinical Pathway/ OR *Clinical Protocol/ OR *Consensus/ OR *Consensus Development/ OR *Health Care Planning/ OR exp *Practice Guideline/ OR (algorithm* OR best evidence OR (best ADJ3 practice*) OR clinical path OR clinical paths OR (clinical ADJ3 pathway*) OR clinical protocol* OR committee opinion* OR CPG OR CPGs OR consensus OR (critical ADJ3 pathway*) OR gold standard* OR guidance* OR guideline* OR guide line* OR policy statement* OR position statement* OR practical guide* OR practice parameter* OR practice pathway* OR practice protocol* OR practice standard* OR recommendation* OR standard care* OR standard of care OR standards of care).ti,bt |
| 28 | (dosage* OR dose* OR dosing OR drug OR drugs OR manag* OR medication* OR pharmaceutic* OR pharmaco* OR therap* OR treat*).ti |
| 29 | 19 AND 27 |
| 30 | 29 AND (23 OR 24 OR 26 OR 28) |
| 31 | *Biomedical Technology Assessment/ OR *Meta Analysis/ OR *"Meta Analysis (topic)"/ OR *Systematic Review/ OR *"Systematic Review (topic)"/ OR (hta or htas OR evidence base* OR evidence report* OR evidence synthesis OR evidence syntheses OR meta-analy* OR metaanaly* OR met analy* OR metanaly* OR meta regression* OR metaregression* OR meta review* OR metareview* OR meta synthesis OR metasynthesis OR overview of review* OR (systematic* ADJ3 (review* OR overview* OR search* OR research*)) OR research evidence* OR technology appraisal* OR technology assessment* OR technology overview* OR technology reassessment* OR umbrella review*).ti,ab. OR (review.tw. AND ((medline OR pubmed) AND (cochrane OR embase)).ti,ab) |
| 32 | 19 AND 31 |
| 33 | 32 AND (23 OR 24 OR 26) |
| 34 | 30 OR 33 |
| 35 | limit 34 to yr="2016 - 2021" |
| 36 | (cmin OR dosage* OR dose* OR dosing OR escalation OR induction* OR intensification OR monitor* OR tdm).ti,ab |
| 37 | 19 AND 36 |
| 38 | 37 AND (24 OR 25) |
| 39 | limit 38 to yr="2000 - 2021" |
| 40 | 35 OR 39 |
| 41 | Case Report/ OR Editorial/ OR Letter/ OR (case report* OR case stud* OR case series OR comment* OR reply OR replies OR editorial* OR letter*).ti |
| 42 | 40 NOT 41 |
| 43 | Nonhuman/ NOT (Human/ AND Nonhuman/) |
| 44 | 42 NOT 43 |
| 45 | Conference Abstract.pt |
| 46 | 44 NOT 45 |

| | |
|---|---|
| **EBM Reviews (Ovid) : Cochrane Database of Systematic Reviews; Health Technology Assessment; NHS Economic Evaluation Database**<br>**Date du repérage : juin 2021**<br>**Limites : 2016- (2000- NHS Economic Evaluation Database) ; anglais, français** | |
| 1 | (colitis gravis OR crohn disease OR crohns disease OR crohn's disease OR crohn's enteritis OR enteritis regionalis OR granulomatous colitis OR granulomatous enteritis OR ibd OR idiopathic proctocolitis OR ileocolitis OR inflammatory bowel disease* OR morbus crohn OR regional enteritis OR regional enterocolitis OR regional ileitis OR terminal ileitis OR ulcerative colitis).ti,ab |
| 2 | (adult-onset still's disease OR adult onset still disease OR arthritis deformans OR arthrosis deformans OR beauvais disease OR caplan syndrome OR chronic articular rheumatism OR felty syndrome OR inflammatory arthritis OR rheumarthritis OR rheumatic arthritis OR rheumatic polyarthritis OR rheumatoid arthritis OR rheumatoid nodule OR rheumatoid vasculitis OR sjogren's syndrome).ti,ab |
| 3 | ((juvenile ADJ3 (arthritis OR chronic arthritis OR enthesitis-related arthritis OR idiopathic arthritis OR oligoarthritis OR onset still disease OR onset stills disease OR onset still's disease OR polyarthritis OR psoriatic arthritis OR rheumatoid arthritis OR rheumatoid polyarthritis OR systemic arthritis)) OR arthritis deformans juvenilis OR chronic juvenile arthritis OR juvenile arthropathy).ti,ab |
| 4 | (((psoriasis OR psoriatic*) ADJ1 (arthritic OR arthritis OR arthropathic* OR arthropath* OR polyarthritis OR rheumatism OR rheumatoid arthritis)) OR alibert bazin disease).ti,ab |
| 5 | (ankylating spondylitis OR ankylopoietic spondyl* ORankylosing spine OR ankylosing spondilitis OR ankylosing spondyl* OR ankylosis spondylitis OR ankylotic spondylitis OR bechterew disease OR bechterews disease OR bechterew's disease OR bekhterev disease OR marie-struempell disease OR morbus bechterew OR rheumatoid spondylitis OR spinal ankylosis OR spine ankylosis OR spondylarthritis ankylopoietica OR spondylarthritis ankylosans OR spondylarthrosis ankylopoietica OR spondylitis ankylopoietica OR spondyloarthritis ankylopoietica OR vertebral ankylosis).ti,ab |
| 6 | (psorias* OR psoriatic*).ti,ab |
| 7 | 1 OR 2 OR 3 OR 4 OR 5 OR 6 |
| 8 | (anti-tnf* OR (tnf* ADJ3 (antagonist* OR block* OR inhibitor*)) OR (anti ADJ (il-17 OR interleukin-17 OR il-17a OR interleukin-17a OR il-12 OR interleukin-12 OR il-23 OR interleukin-23 OR il-6 OR interleukin-6)) OR (anti ADJ (cd80 OR cd86 OR (itga4 AND itgb7) OR cd20)) OR ((il-17 OR interleukin-17 OR il-17a OR interleukin-17a OR il-12 OR interleukin-12 OR il-23 OR interleukin-23 OR il-6 OR interleukin-6 OR cd80 OR cd86 OR itga4 OR itgb7 OR cd20) ADJ3 (antagonist* OR block* OR inhibitor*))).ti,ab |
| 9 | (biologic agent* OR biologic drug* OR biologic medicine* OR biologic pharmaceutic* OR biologic product* OR biologic therap* OR biologic treatment* OR biological drug* OR biological medicine* OR biological product* OR biological therap* OR biological treatment* OR biologicals OR biologics OR biomedicament* OR biomedicine* OR bio-medicine* OR biopharmaceutic* OR bio-pharmaceutic* OR biosimilar* OR bio-similar* OR biotherap* OR bio-therap* OR originator* OR reference biologic* OR reference product*).ti,ab |
| 10 | (abatacept OR actemra OR adalimumab OR amjevita OR atlizumab OR belatacept OR brodalumab OR certolizumab pegol OR cimzia OR cosentyx OR cyltezo OR enbrel OR entyvio OR erelzi OR etanercept OR golimumab OR guselkumab OR humira OR inflectra OR infliximab OR ixekizumab OR kevzara OR mabthera OR monoclonal antibod* OR nulojix OR orencia OR remicade OR renflexis OR rituxan OR rituximab OR risankizumab OR roactemra OR sarilumab OR secukinumab OR siliq OR simponi OR skyrizi OR stelara OR taltz OR tocilizumab OR tremfya OR ustekinumab OR vedolizumab).ti,ab |
| 11 | 8 OR 9 OR 10 |
| 12 | 7 AND 11 |

| MEDLINE (Ovid)<br>Date du repérage : 17 septembre 2021<br>Limites : 2000- (ligne 20 : 2016-) ; anglais, français | |
|---|---|
| 1 | Dermatitis, Atopic/dt |
| 2 | (atopic constitutional neurodermatitis OR atopic dermatiti* OR atopic eczema OR atopic neurodermatiti* OR coca sulzberger disease OR coca sulzberger syndrome OR disseminated neurodermatiti* OR eczema atopica OR eczema endogenous OR eczema infantum OR endogenous eczema OR infantile eczema OR neurodermatitis constitutionalis OR neurodermatitis disseminata).ti,ab,kf |
| 3 | 1 OR 2 |
| 4 | Dupilumab/dt |
| 5 | (dupilumab OR dupixent OR regn668 OR regn-668 OR sar231893 OR sar-231893).mp |
| 6 | 4 OR 5 |
| 7 | (cmin OR dosage* OR dose* OR dosing OR escalation OR induction* OR intensification OR monitor* OR tdm).mp |
| 8 | 3 AND 6 AND 7 |
| 9 | exp *Biological Products/ad,tu |
| 10 | (il-4 OR interleukin-4 OR il-13 OR interleukin-13).ti,ab |
| 11 | (biologic agent* OR biologic drug* OR biologic medicine* OR biologic pharmaceutic* OR biologic product* OR biologic therap* OR biologic treatment* OR biological drug* OR biological medicine* OR biological product* OR biological therap* OR biological treatment* OR biologicals OR biologics OR biomedicament* OR biomedicine* OR bio-medicine* OR biopharmaceutic* OR bio-pharmaceutic* OR biosimilar* OR bio-similar* OR biotherap* OR bio-therap* OR originator* OR reference biologic* OR reference product*).ti,ab |
| 12 | 9 OR 10 OR 11 |
| 13 | exp Guidelines as Topic/ OR exp Guideline/ OR Health Planning Guidelines/ OR exp Consensus/ OR exp Consensus Development Conference/ OR exp Consensus Development Conferences as Topic/ OR exp Critical Pathways/ OR Clinical Conference.pt OR exp Algorithms/ OR exp Clinical Protocols/ OR (guideline* OR guide line* OR cpg or cpgs OR guidance OR practical guide* OR (best ADJ3 practice*) OR (evidence ADJ2 (base* OR report* OR synthes* OR research OR practice* OR best)) OR consensus OR algorithm* OR (clinical ADJ2 (path OR paths OR pathway* OR protocol*)) OR ((critical OR clinical) ADJ2 (path OR paths OR pathway*)) OR recommendation* OR committee opinion* OR policy statement* OR position statement* OR practice parameter* OR practice pathway* OR practice protocol* OR ((standard OR standards) ADJ2 (care* OR practice*)) OR (gold ADJ2 standard*)).ti,bt |
| 14 | (dosage* OR dose* OR dosing OR drug OR drugs OR manag* OR medication* OR pharmaceutic* OR pharmaco* OR therap* OR treat*).ti |
| 15 | 3 AND 13 |
| 16 | 15 AND (12 OR 14) |
| 17 | Meta-Analysis.pt OR exp Meta-Analysis as Topic/ OR Systematic Review/ OR exp Technology Assessment, Biomedical/ OR (meta-analy* OR metaanaly* OR met analy* OR metanaly* OR meta-review* OR metareview* OR meta regression* OR metaregression* OR meta synthesis OR metasynthesis OR overview of review* OR overviews of reviews OR (systematic* ADJ3 (review* OR overview* OR literature OR search* OR research*)) OR ((quantitative OR methodologic* OR integrativ*) ADJ (review* OR overview* OR synthes*)) OR umbrella review* OR hta or htas OR technology assessment* OR technology overview* OR technology appraisal* OR technology reassessment*).ti,ab,kw OR (review.mp AND ((medline OR pubmed) AND (cochrane OR embase)).ti,ab,kw) |
| 18 | 3 AND 17 AND 12 |
| 19 | 16 OR 18 |
| 20 | limit 19 to yr="2016 - 2021" |
| 21 | limit 8 to yr="2000 - 2021" |
| 22 | 20 OR 21 |
| 23 | Case Reports/ OR Comment/ OR Editorial/ OR Letter/ OR (case report* OR case stud* OR case series OR comment* OR reply OR replies OR editorial* OR letter*).ti |
| 24 | 22 NOT 23 |
| 25 | Animals/ NOT (Humans/ AND Animals/) |
| 26 | 24 NOT 25 |

| Embase (Ovid)<br>Date du repérage : 17 septembre 2021<br>Limites : 2000- (ligne 20 : 2016-) ; anglais, français | |
|---|---|
| 1 | Atopic Dermatitis/dt |
| 2 | (atopic constitutional neurodermatitis OR atopic dermatiti* OR atopic eczema OR atopic neurodermatiti* OR coca sulzberger disease OR coca sulzberger syndrome OR disseminated neurodermatiti* OR eczema atopica OR eczema endogenous OR eczema infantum OR endogenous eczema OR infantile eczema OR neurodermatitis constitutionalis OR neurodermatitis disseminata).ti,ab,kw |
| 3 | 1 OR 2 |
| 4 | Dupilumab/ |
| 5 | (dupilumab OR dupixent OR regn668 OR regn-668 OR sar231893 OR sar-231893).mp |
| 6 | 4 OR 5 |
| 7 | (cmin OR dosage* OR dose* OR dosing OR escalation OR induction* OR intensification OR monitor* OR tdm).mp |
| 8 | 3 AND 6 AND 7 |
| 9 | exp *Biological Product/ |
| 10 | (il-4 OR interleukin-4 OR il-13 OR interleukin-13).ti,ab |
| 11 | (biologic agent* OR biologic drug* OR biologic medicine* OR biologic pharmaceutic* OR biologic product* OR biologic therap* OR biologic treatment* OR biological drug* OR biological medicine* OR biological product* OR biological therap* OR biological treatment* OR biologicals OR biologics OR biomedicament* OR biomedicine* OR bio-medicine* OR biopharmaceutic* OR bio-pharmaceutic* OR biosimilar* OR bio-similar* OR biotherap* OR bio-therap* OR originator* OR reference biologic* OR reference product*).ti,ab |
| 12 | 9 OR 10 OR 11 |
| 13 | *Algorithm/ OR *Clinical Pathway/ OR *Clinical Protocol/ OR *Consensus/ OR *Consensus Development/ OR *Health Care Planning/ OR exp *Practice Guideline/ OR (algorithm* OR best evidence OR (best ADJ3 practice*) OR clinical path OR clinical paths OR (clinical ADJ3 pathway*) OR clinical protocol* OR committee opinion* OR CPG OR CPGs OR consensus OR (critical ADJ3 pathway*) OR gold standard* OR guidance* OR guideline* OR guide line* OR policy statement* OR position statement* OR practical guide* OR practice parameter* OR practice pathway* OR practice protocol* OR practice standard* OR recommendation* OR standard care* OR standard of care OR standards of care).ti,bt |
| 14 | (dosage* OR dose* OR dosing OR drug OR drugs OR manag* OR medication* OR pharmaceutic* OR pharmaco* OR therap* OR treat*).ti |
| 15 | 3 AND 13 |
| 16 | 15 AND (12 OR 14) |
| 17 | *Biomedical Technology Assessment/ OR *Meta Analysis/ OR *"Meta Analysis (topic)"/ OR *Systematic Review/ OR *"Systematic Review (topic)"/ OR (hta or htas OR evidence base* OR evidence report* OR evidence synthesis OR evidence syntheses OR meta-analy* OR metaanaly* OR met analy* OR metanaly* OR meta regression* OR metaregression* OR meta review* OR metareview* OR meta synthesis OR metasynthesis OR overview of review* OR (systematic* ADJ3 (review* OR overview* OR search* OR research*)) OR research evidence* OR technology appraisal* OR technology assessment* OR technology overview* OR technology reassessment* OR umbrella review*).ti,ab. OR (review.tw. AND ((medline OR pubmed) AND (cochrane OR embase)).ti,ab) |
| 18 | 3 AND 17 AND 12 |
| 19 | 16 OR 18 |
| 20 | limit 19 to yr="2016 - 2021" |
| 21 | limit 8 to yr="2000 - 2021" |
| 22 | 20 OR 21 |
| 23 | Case Report/ OR Editorial/ OR Letter/ OR (case report* OR case stud* OR case series OR comment* OR reply OR replies OR editorial* OR letter*).ti |
| 24 | 22 NOT 23 |
| 25 | Nonhuman/ NOT (Human/ AND Nonhuman/) |
| 26 | 24 NOT 25 |
| 27 | Conference Abstract.pt |
| 28 | 26 NOT 27 |

| **EBM Reviews (Ovid) : Cochrane Database of Systematic Reviews; Health Technology Assessment; NHS Economic Evaluation Database**<br>**Date du repérage : 17 septembre 2021**<br>**Limites : 2016- (2000- NHS Economic Evaluation Database) ; anglais, français** | |
|---|---|
| 1 | (atopic constitutional neurodermatitis OR atopic dermatiti* OR atopic eczema OR atopic neurodermatiti* OR coca sulzberger disease OR coca sulzberger syndrome OR disseminated neurodermatiti* OR eczema atopica OR eczema endogenous OR eczema infantum OR endogenous eczema OR infantile eczema OR neurodermatitis constitutionalis OR neurodermatitis disseminata).ti,ab,kw |
| 2 | (dupilumab OR dupixent OR regn668 OR regn-668 OR sar231893 OR sar-231893).mp |
| 3 | (il-4 OR interleukin-4 OR il-13 OR interleukin-13).ti,ab |
| 4 | (biologic agent* OR biologic drug* OR biologic medicine* OR biologic pharmaceutic* OR biologic product* OR biologic therap* OR biologic treatment* OR biological drug* OR biological medicine* OR biological product* OR biological therap* OR biological treatment* OR biologicals OR biologics OR biomedicament* OR biomedicine* OR bio-medicine* OR biopharmaceutic* OR bio-pharmaceutic* OR biosimilar* OR bio-similar* OR biotherap* OR bio-therap* OR originator* OR reference biologic* OR reference product*).ti,ab |
| 5 | 1 AND (2 OR 3 OR 4) |

**Sites Web, registres d'essais cliniques et autres sources**

Recherche effectuée entre mai 2021 et septembre 2021 avec les mots clés « guideline », « dose optimisation » ou « biologic agent », en utilisant le moteur de recherche Google et en visitant les sites suivants :

- Agency for Healthcare Research and Quality (AHRQ) https://www.ahrq.gov/research/findings/evidence-based-reports/search.html
- Agence canadienne des médicaments et des technologies/Canadian Agency for Drugs and Technologies in Health (ACMTS/CADTH) https://www.cadth.ca/fr
- Australian Clinical Practice Guidelines (NHMRC) https://www.clinicalguidelines.gov.au/
- BCGuidelines.ca http://www.bcguidelines.ca/
- Centre fédéral d'expertise des soins de santé (KCE) https://kce.fgov.be/fr
- ECRI Guidelines Trust https://guidelines.ecri.org/
- Guidelines International Network (G-I-N) https://g-i-n.net/
- Haute Autorité de Santé (HAS) https://www.has-sante.fr/jcms/c_6056/fr/recherche-avancee
- Health Quality Ontario (HQO) https://hqontario.ca/Evidence-to-Improve-Care/Quality-Standards
- Infobanque AMC (Association médicale canadienne – Canadian Medical Association) https://jouleamc.ca/cpg/homepage
- Institute for Clinical Evaluative Sciences https://www.ices.on.ca/
- Institute of Health Economics (IHE) https://www.ihe.ca/
- International Network of Agencies for Health Technology Assessment (INAHTA) https://www.inahta.org/
- New Zealand Guidelines Group (NZGG) https://www.health.govt.nz/about-ministry/ministry-health-websites/new-zealand-guidelines-group
- NHS National Institute for Health and Care Excellence (NICE) https://www.nice.org.uk/guidance
- Scottish Intercollegiate Guidelines Network (SIGN) https://www.guidelinesinpractice.co.uk/home
- The Campbell Collaboration Library of Systematic Reviews https://www.campbellcollaboration.org/
- World Health Organization (WHO) https://www.who.int/

# ANNEXE B

## Sélection des documents

**Figure B-1 Diagramme de flux pour la gastro-entérologie, la rhumatologie et le psoriasis en plaques**

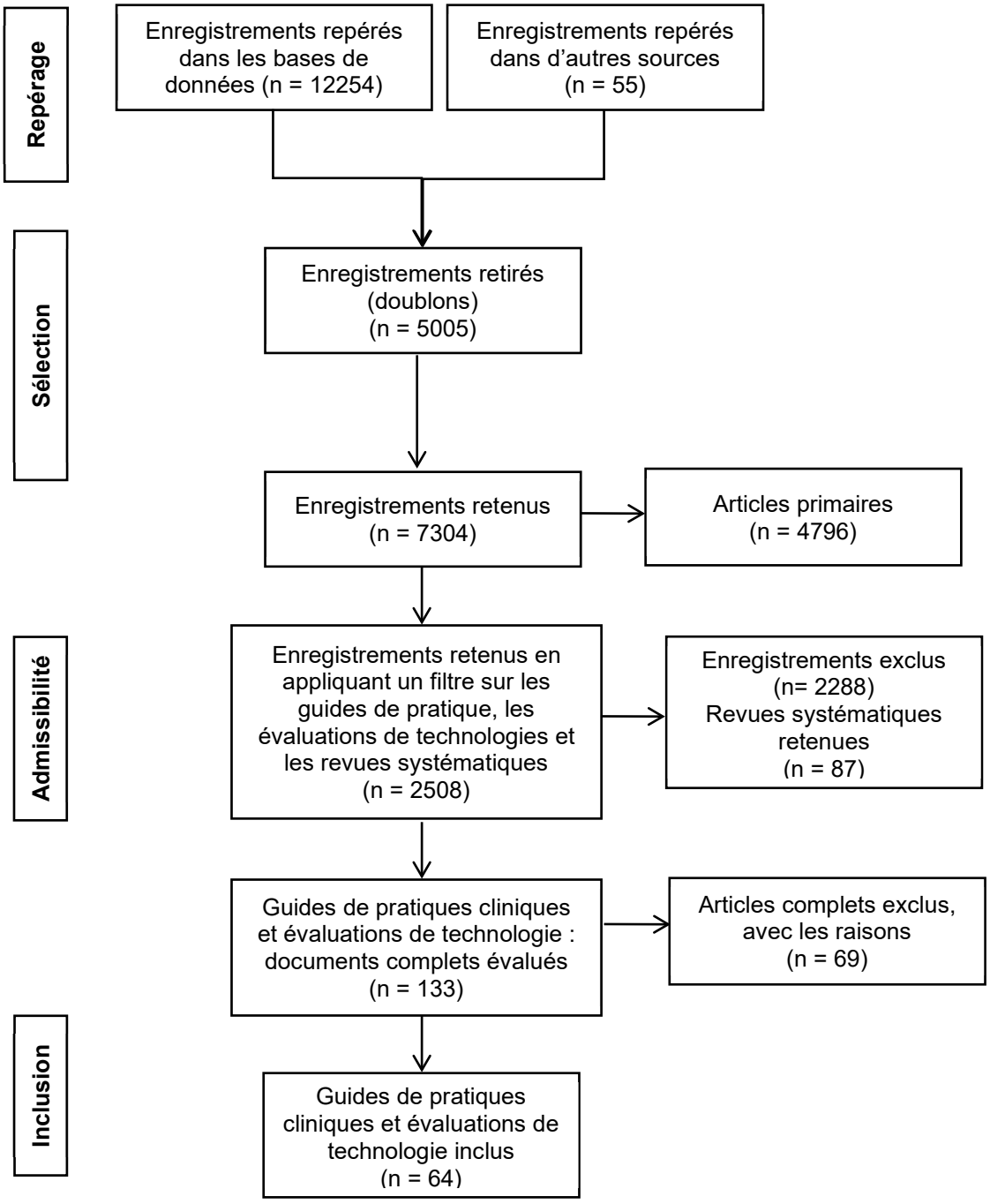

**Figure B-2 Diagramme de flux pour la dermatite atopique**

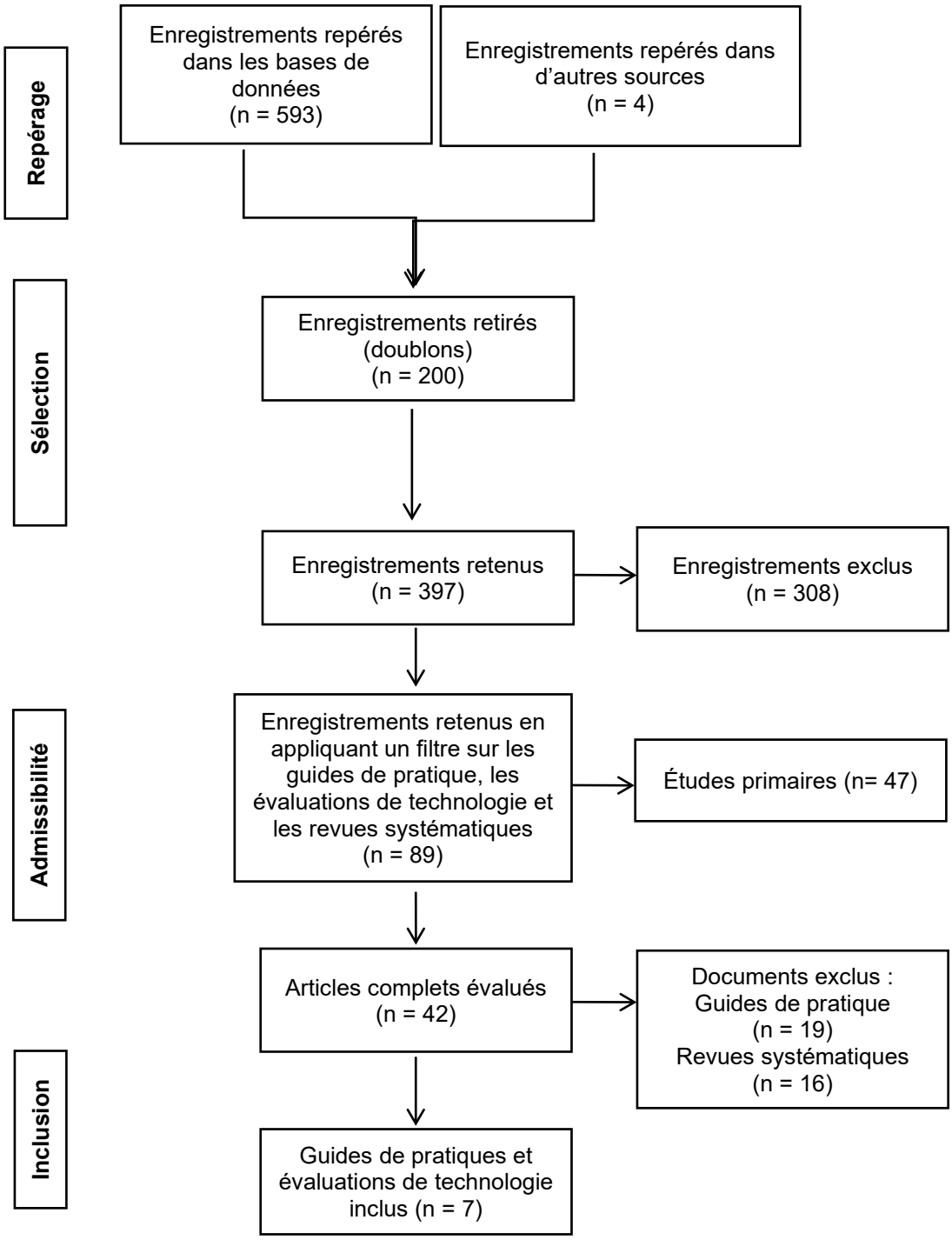

**Tableau B-1 Liste des documents contenant des recommandations qui ont été sélectionnés pour les travaux**

| **Titres et références** (par ordre alphabétique du nom du 1er auteur) | **Type de document** |
|---|---|
| **Maladie de Crohn chez l'adulte** | |
| Chao et Visintini, 2018 | Évaluation de technologie |
| Feuerstein *et al.*, 2017 | Guide de pratique clinique |
| Feuerstein *et al.*, 2021 | Guide de pratique clinique |
| Lamb *et al.*, 2019 | Guide de pratique clinique |
| NICE, 2015c | Évaluation de technologie |
| NICE, 2017a | Évaluation de technologie |
| NICE, 2018h | Évaluation de technologie |
| Ooi *et al.*, 2019 | Guide de pratique clinique |
| Panaccione *et al.*, 2019 | Guide de pratique clinique |
| Park *et al.*, 2017 | Guide de pratique clinique |
| Torres *et al.*, 2020a | Guide de pratique clinique |
| **Colite ulcéreuse chez l'adulte** | |
| Chao et Visintini, 2018 | Évaluation de technologie |
| Choi *et al.*, 2017 | Guide de pratique clinique |
| Feuerstein *et al.*, 2017 | Guide de pratique clinique |
| Feuerstein *et al.*, 2020 | Consensus d'experts |
| Harbord *et al.*, 2017 | Guide de pratique clinique |
| Lamb *et al.*, 2019 | Guide de pratique clinique |
| NICE, 2015a | Évaluation de technologie |
| NICE, 2018g | Évaluation de technologie |
| NICE, 2020b | Évaluation de technologie |
| Ooi *et al.*, 2019 | Guide de pratique clinique |
| **Maladie de Crohn pédiatrique** | |
| Mack *et al.*, 2019 | Guide de pratique clinique |
| Van Rheenen *et al.*, 2021 | Guide de pratique clinique |
| **Polyarthrite rhumatoïde chez l'adulte** | |
| Daien *et al.*, 2019 | Guide de pratique clinique |
| Fraenkel *et al.*, 2021 | Guide de pratique clinique |
| NICE, 2014d | Évaluation de technologie |
| NICE, 2020a | Évaluation de technologie |
| NICE, 2021b | Évaluation de technologie |
| NICE, 2021d | Évaluation de technologie |

| **Titres et références** (par ordre alphabétique du nom du 1er auteur) | **Type de document** |
|---|---|
| Smolen *et al.*, 2020 | Guide de pratique clinique |
| **Spondylarthrite ankylosante chez l'adulte** | |
| Hamilton *et al.*, 2017 | Guide de pratique clinique |
| NICE, 2016b | Évaluation de technologie |
| NICE, 2017f | Guide de pratique clinique |
| NICE, 2018f | Évaluation de technologie |
| NICE, 2021c | Évaluation de technologie |
| Park *et al.*, 2020 | Consensus d'experts |
| Tam *et al.*, 2019 | Guide de pratique clinique |
| Van der Heijde *et al.*, 2017 | Guide de pratique clinique |
| Ward *et al.*, 2019 | Guide de pratique clinique |
| Wendling *et al.*, 2018 | Guide de pratique clinique |
| **Arthrite psoriasique chez l'adulte** | |
| Casasola-Vargas *et al.*, 2021 | Guide de pratique clinique |
| Coates *et al.*, 2016 | Guide de pratique clinique |
| Gossec *et al.*, 2020 | Guide de pratique clinique |
| NICE, 2014b | Évaluation de technologie |
| NICE, 2016a | Évaluation de technologie |
| NICE, 2017d | Évaluation de technologie |
| NICE, 2018c | Évaluation de technologie |
| NICE, 2020c | Évaluation de technologie |
| Singh *et al.*, 2019 | Guide de pratique clinique |
| Torre Alonso *et al.*, 2018 | Guide de pratique clinique |
| **Arthrite juvénile idiopatique** | |
| NICE, 2015d | Évaluation de technologie |
| NICE, 2018e | Évaluation de technologie |
| Ringold *et al.*, 2019 | Guide de pratique clinique |
| **Psoriasis en plaques chez l'adulte** | |
| Amatore *et al.*, 2019 | Guide de pratique clinique |
| Canadian Psoriasis Guidelines Addendum Committee, 2016 | Guide de pratique clinique |
| Gisondi *et al.*, 2017 | Guide de pratique clinique |
| Menter *et al.*, 2019 | Guide de pratique clinique |
| NICE, 2010 | Évaluation de technologie |
| NICE, 2014a | Évaluation de technologie |
| NICE, 2014c | Évaluation de technologie |

| **Titres et références** (par ordre alphabétique du nom du 1er auteur) | **Type de document** |
|---|---|
| NICE, 2015b | Évaluation de technologie |
| NICE, 2017b | Évaluation de technologie |
| NICE, 2017c | Évaluation de technologie |
| NICE, 2017e | Guide de pratique clinique |
| NICE, 2018a | Évaluation de technologie |
| NICE, 2018b | Évaluation de technologie |
| NICE, 2019c | Évaluation de technologie |
| Smith *et al.*, 2020 | Guide de pratique clinique |
| **Dermatite atopique** | |
| Agache *et al.*, 2021 | Guide de pratique clinique |
| Agence canadienne des médicaments et des technologies de la santé (ACMTS), 2020 | Évaluation de technologie |
| European Medicines Agency (EMA), Committee for Medicinal Products for Human Use (CHMP), 2020 | Évaluation de technologie |
| Lansang *et al.*, 2019a et Lansang *et al.*, 2019b | Consensus d'experts |
| NICE, 2018d | Évaluation de technologie |
| Werfel *et al.*, 2021 | Guide de pratique clinique |

# ANNEXE C

## Liste des documents exclus et raison de l'exclusion

### Tableau C-1 Documents contenant des recommandations qui ont été exclus et raison de l'exclusion

| **Titres et références** (par ordre alphabétique du nom du 1er auteur) | **Raison de l'exclusion** |
|---|---|
| **Maladie de Crohn chez l'adulte** | |
| Feld *et al.*, 2019 | Absence de résultat d'intérêt |
| Gomollon *et al.*, 2017 | Document plus récent existant |
| Lichtenstein *et al.*, 2018 | Absence de résultat d'intérêt |
| Martins *et al.*, 2019 | Absence de résultat d'intérêt |
| NICE, 2019b | Absence de résultat d'intérêt |
| Wei *et al.*, 2017a | Type de document inadéquat |
| Weizman *et al.*, 2019 | Type de document inadéquat |
| **Maladie de Crohn et colite ulcéreuse chez l'adulte** | |
| Amiot *et al.*, 2021 | Type de document inadéquat |
| Ananthakrishnan *et al.*, 2021 | Type de document inadéquat |
| Biancone *et al.*, 2017 | Absence de résultat d'intérêt |
| Click et Regueiro, 2019 | Type de document inadéquat |
| Inflammatory Bowel Disease Group, 2021 | Type de document inadéquat |
| Khan *et al.*, 2019 | Type de document inadéquat |
| Mitrev *et al.*, 2017 | Type de document inadéquat |
| Nakase *et al.*, 2021 | Absence de résultat d'intérêt |
| Papamichael *et al.*, 2019 | Type de document inadéquat |
| Pinto Pais *et al.*, 2020 | Type de document inadéquat |
| Ran *et al.*, 2021 | Type de document inadéquat |
| Varma *et al.*, 2017 | Type de document inadéquat |
| Vulliemoz *et al.*, 2020 | Type de document inadéquat |
| **Colite ulcéreuse chez l'adulte** | |
| Abdulrazeg *et al.*, 2019 | Absence de résultat d'intérêt |
| Glick *et al.*, 2020 | Absence de résultat d'intérêt |
| Ko *et al.*, 2019 | Absence de résultat d'intérêt |
| Kucharzik *et al.*, 2020 | Type de document inadéquat |
| Magro *et al.*, 2017 | Absence de résultat d'intérêt |
| NICE, 2019a | Absence de résultat d'intérêt |

| **Titres et références** (par ordre alphabétique du nom du 1er auteur) | **Raison de l'exclusion** |
|---|---|
| Rubin *et al.*, 2019 | Type de document inadéquat |
| Teixeira *et al.*, 2019 | Type de document inadéquat |
| Wei *et al.*, 2017b | Type de document inadéquat |
| **Polyarthrite rhumatoïde chez l'adulte** | |
| Allen *et al.*, 2018 | Type de document inadéquat |
| Cardiel *et al.*, 2021 | Absence de résultat d'intérêt |
| Duarte *et al.*, 2017 | Type de document inadéquat |
| Ho *et al.*, 2019 | Type de document inadéquat |
| Holroyd *et al.*, 2019 | Absence de résultat d'intérêt |
| Lau *et al.*, 2019 | Absence de résultat d'intérêt |
| Mota *et al.*, 2018 | Type de document inadéquat |
| Rosas *et al.*, 2020 | Type de document inadéquat |
| Stoilov *et al.*, 2020 | Type de document inadéquat |
| Tornero Molina *et al.*, 2020 | Type de document inadéquat |
| Vassilopoulos *et al.*, 2020 | Type de document inadéquat |
| **Spondylarthrite ankylosante chez l'adulte** | |
| Ivanova et Stoilov, 2020 | Type de document inadéquat |
| Machado *et al.*, 2017 | Type de document inadéquat |
| Smolen *et al.*, 2018 | Absence de résultat d'intérêt |
| **Arthrite psoriasique chez l'adulte** | |
| Garcia-Vicuna *et al.*, 2021 | Absence de résultat d'intérêt |
| Kavanaugh *et al.*, 2020 | Type de document inadéquat |
| Maharaj et Chandran, 2017 | Type de document inadéquat |
| Marchesoni *et al.*, 2017 | Type de document inadéquat |
| Orbai, 2020 | Type de document inadéquat |
| Tsai *et al.*, 2021 | Type de document inadéquat |
| **Arthrite juvénile idiopathique** | |
| Ho *et al.*, 2020 | Type de document inadéquat |
| Okamoto *et al.*, 2019 | Type de document inadéquat |
| Ravelli *et al.*, 2018 | Absence de résultat d'intérêt |
| Santos *et al.*, 2016 | Type de document inadéquat |
| **Psoriasis en plaques chez l'adulte** | |
| Arnone *et al.*, 2019 | Type de document inadéquat |
| Cordoro, 2020 | Type de document inadéquat |
| De la Brassinne *et al.*, 2016 | Type de document inadéquat |

| **Titres et références** (par ordre alphabétique du nom du 1er auteur) | **Raison de l'exclusion** |
|---|---|
| Eisert *et al.*, 2019a | Population non visée par les travaux |
| Eisert *et al.*, 2019b | Population non visée par les travaux |
| Elmets *et al.*, 2019 | Absence de résultat d'intérêt |
| Kogan *et al.*, 2019 | Absence de résultat d'intérêt |
| Kolios *et al.*, 2016 | Type de document inadéquat |
| Lansang *et al.*, 2020 | Population non visée par les travaux |
| Menter *et al.*, 2020 | Population non visée par les travaux |
| Mijuskovic *et al.*, 2016 | Type de document inadéquat |
| Nast *et al.*, 2020 | Absence de résultat d'intérêt |
| Nast *et al.*, 2021 | Absence de résultat d'intérêt |
| Ormerod, 2019 | Type de document inadéquat |
| Podoswa-Ozerkovsky *et al.*, 2020 | Type de document inadéquat |
| Reich *et al.*, 2020a | Type de document inadéquat |
| Reich *et al.*, 2020b | Type de document inadéquat |
| Saeki *et al.*, 2020 | Type de document inadéquat |
| Torres *et al.*, 2020b | Type de document inadéquat |
| Tsai et Tsai, 2020 | Type de document inadéquat |
| Wu et Valdecantos, 2017 | Type de document inadéquat |
| **Dermatite atopique – documents contenant des recommandations** | |
| Boguniewicz *et al.*, 2018 | Type de document inadéquat |
| Chan *et al.*, 2021 | Type de document inadéquat |
| Howell *et al.*, 2020 | Type de document inadéquat |
| Katoh *et al.*, 2019 | Type de document inadéquat |
| Kulthanan *et al.*, 2021 | Type de document inadéquat |
| NICE, 2021a | Absence de résultat d'intérêt |
| Nowicki *et al.*, 2020a | Type de document inadéquat |
| Nowicki *et al.*, 2020b | Type de document inadéquat |
| Nowicki *et al.*, 2020c | Type de document inadéquat |
| Rajagopalan *et al.*, 2019 | Absence de résultat d'intérêt |
| Russo *et al.*, 2020 | Type de document inadéquat |
| Saeki *et al.*, 2016 | Type de document inadéquat |
| Sastre *et al.*, 2020 | Type de document inadéquat |

| **Titres et références** (par ordre alphabétique du nom du 1er auteur) | **Raison de l'exclusion** |
|---|---|
| Werfel *et al.*, 2016 | Absence de résultat d'intérêt |
| Wollenberg *et al.*, 2018a et Wollenberg *et al.*, 2018b | Type de document inadéquat |
| Wollenberg *et al.*, 2020 | Type de document inadéquat |
| Wong *et al.*, 2017 | Type de document inadéquat |
| Yang *et al.*, 2021 | Type de document inadéquat |

# ANNEXE D

## Tableaux exhaustifs des résultats

Une synthèse des informations relatives aux posologies recommandées et aux possibilités d'intensification de ces dernières issues des monographies de produit des médicaments biologiques concernés (médicament de référence et biosimilaires éventuels) a été réalisée dans les tableaux ci-dessous à des fins de concision et de pertinence.

**Tableau D-1 Information extraite des indications de remboursement du Québec et des monographies de produits pour la maladie de Crohn chez l'adulte**

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Adalimumab | Autorisation initiale : induction à raison de 160 mg initialement et 80 mg à la 2e semaine et entretien à la dose de 40 mg aux 2 semaines.<br><br>Renouvellement : période maximale de 12 mois.<br><br>Augmentation : 40 mg par semaine à partir de la 12e semaine de traitement, et ce, pour 3 mois. Renouvellement possible d'une durée maximale de 12 mois. | Induction : 160 mg à la semaine 0 (4 x 40 mg x 1 jour ou 2 x 40 mg x 2 jours) et 80 mg à la semaine 2 (2 x 40 mg x 1 jour).<br><br>Entretien : 40 mg toutes les 2 semaines à compter de la semaine 4.<br><br>Chez les patients qui présentent une poussée de la maladie, l'augmentation de la fréquence d'administration peut être envisagée.<br><br>Augmentation : Certains patients qui n'ont pas répondu au traitement par l'adalimumab injectable à la semaine 4 (phase d'induction) pourraient bénéficier d'un traitement d'entretien jusqu'à la semaine 12. |
| Infliximab | Autorisation initiale : maximum de 3 doses de 5mg/kg.<br><br>Renouvellement : période de 12 mois, **pas de dose maximale ni d'intervalle posologique minimal** pour le traitement d'entretien. | Induction : 5 mg/kg aux semaines 0, 2 et 6,<br><br>Entretien : une dose de 5 mg/kg toutes les 8 semaines.<br><br>Augmentation : Chez les patients dont la réponse n'est pas satisfaisante, il est possible d'augmenter la dose jusqu'à 10 mg/kg. Certains patients adultes ne tireront aucun avantage thérapeutique d'une augmentation de dose. En plus de l'évaluation clinique du médecin, la mesure des creux sériques d'infliximab et des titres d'anticorps anti-infliximab doivent être pris en compte avant d'envisager un ajustement de la dose |

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Védolizumab | Autorisation initiale : période maximale de 3 mois.<br>Maximum de 3 doses de 300 mg administrées aux semaines 0, 2 et 6.<br><br>Renouvellement : À raison de 300 mg toutes les 8 semaines pour une période maximale de 12 mois. | Induction : 300 mg administrés par voie intraveineuse aux semaines 0, 2 et 6<br><br>Entretien : 300 mg toutes les huit semaines.<br><br>Le traitement doit être abandonné chez les patients qui ne retirent aucun bienfait thérapeutique après 14 semaines. Au cours du traitement d'entretien, la dose de corticostéroïdes peut être diminuée graduellement, conformément aux lignes directrices de pratique clinique. |

**Tableau D-2 Information extraite des critères de remboursement du Québec et des monographies de produits pour la colite ulcéreuse chez l'adulte**

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Adalimumab | Autorisation initiale : période maximale de 4 mois.<br>Pas de dose maximale ni d'intervalle posologique spécifiés.<br>Renouvellement : période maximale de 12 mois | Induction: 160 mg à la semaine 0 (4 x 40 mg x 1 jour ou 2 x 40 mg x 2 jours) et 80 mg à la semaine 2 (2 x 40 mg x 1 jour).<br>Entretien : 40 mg toutes les 2 semaines à compter de la semaine 4.<br>Poursuite : Chez les personnes ayant obtenu une réponse au cours des 8 premières semaines de traitement. |
| Infliximab | Autorisation initiale : pour une période maximale de 4 mois<br>Pas de dose maximale ni d'intervalle posologique spécifiés.<br>Renouvellement : pour une période maximale de 12 mois | Induction : 5 mg/kg aux semaines 0, 2 et 6.<br>Entretien : 5 mg/kg toutes les 8 semaines.<br>Augmentation : Chez certaines personnes adultes, il est possible d'augmenter la dose jusqu'à 10 mg/kg pour maintenir la réponse clinique et la rémission. Certaines personnes adultes ne tireront aucun avantage thérapeutique d'une augmentation de la dose. En plus de l'évaluation clinique du médecin, la mesure des creux sériques d'infliximab et des titres d'anticorps anti-infliximab doit être prise en compte avant d'envisager un ajustement de la dose. |
| Védolizumab | Autorisation initiale : période maximale de 4 mois<br>Dosage : 300 mg aux semaines 0, 2 et 6, puis toutes les 8 semaines<br>Renouvellement : période maximale de 12 mois | 300 mg aux semaines 0, 2 et 6, puis toutes les huit semaines par la suite.<br>Arrêt : Le traitement doit être abandonné chez les patients qui ne retirent aucun bienfait thérapeutique après 10 semaines. |

**Tableau D-3 Information extraite des critères de remboursement du Québec et des monographies de produits pour maladie de Crohn pédiatrique**

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Infliximab | Autorisation initiale : maximum de 3 doses de 5mg/kg<br>Pas de dose maximale ni d'intervalle posologique spécifiés.<br>Renouvellement : période de 12 mois | Induction : 5 mg/kg administrée comme traitement d'induction aux semaines 0, 2 et 6.<br>Entretien : doses de 5 mg/kg toutes les 8 semaines.<br>Augmentation : Les patients qui n'auront pas répondu au traitement à la semaine 14 sont peu susceptibles d'y répondre même si l'on continue à leur administrer ce médicament. Dans de tels cas, il convient d'envisager l'arrêt du traitement. |

**Tableau D-4 Information extraite des critères de remboursement du Québec et des monographies de produits pour la polyarthrite rhumatoïde chez l'adulte**

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Adalimumab | Autorisation initiale : période maximale de 5 mois à raison de 40 mg aux 2 semaines.<br><br>Augmentation : 40 mg par semaine après 12 semaines pour les patients recevant l'adalimumab en monothérapie.<br><br>Renouvellement : période maximale de 12 mois. | 40 mg toutes les 2 semaines par injection sous-cutanée.<br><br>Les données disponibles laissent entendre qu'on obtient habituellement une réponse clinique à l'intérieur de 12 semaines de traitement. Il faut reconsidérer soigneusement la poursuite du traitement chez la personne qui ne répond pas au traitement au cours de cette période. |
| Certolizumab pegol | 400 mg aux semaines 0, 2 et 4, suivies de 200 mg toutes les 2 semaines ou de 400 mg toutes les 4 semaines. | Dose d'attaque: La dose d'attaque recommandée chez l'adulte est de 400 mg (2 injections sous-cutanées à 200 mg) au départ (semaine 0), la semaine 2 et la semaine 4.<br><br>Dose d'entretien : Après la dose d'attaque, la dose d'entretien recommandée chez l'adulte atteint de polyarthrite rhumatoïde est de 200 mg toutes les 2 semaines. On peut aussi envisager de prescrire le certlozimab à 400 mg toutes les 4 semaines. |
| Étanercept | 50 mg par semaine. | 50 mg par semaine<br><br>La dose de 50 mg doit être administrée en une seule injection sous-cutanée. La dose de 50 mg peut également être administrée en deux injections sous-cutanées de 25 mg, auquel cas les deux injections doivent être données soit une fois par semaine le même jour ou à trois ou quatre jours d'écart.<br><br>Augmentation : Comme une étude portant sur l'administration de 50 mg d'étanercept deux fois par semaine à des patients atteints de polyarthrite rhumatoïde semble indiquer une incidence plus élevée d'effets indésirables avec des taux de réponse similaires, les posologies supérieures à 50 mg par semaine ne sont pas recommandées. |

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Golimumab | Posologie par voie sous-cutanée : Les autorisations sont données à raison de 50 mg par mois.<br><br>Posologie par voie intraveineuse : Les autorisations sont données à raison de 2mg/kg aux semaines 0 et 4, puis à 2mg/kg toutes les 8 semaines | Posologie par voie sous-cutanée : 50 mg, une fois par mois, à la même date chaque mois.<br><br>Posologie par voie intraveineuse : 2 mg/kg administré en une perfusion intraveineuse de 30 minutes aux semaines 0 et 4, et toutes les 8 semaines par la suite.<br><br>Augmentation : La monographie de Simponi$^{MC}$ souligne que les données tirées des études cliniques sur la polyarthrite rhumatoïde semblent indiquer que l'efficacité du golimumab ne s'accroît pas à des doses supérieures à 50 mg.<br><br>Arrêt : Les données disponibles provenant des études cliniques suggèrent que la réponse clinique est généralement atteinte dans les 14 à 16 semaines de traitement (après 4 doses). Il importe de bien réfléchir à la poursuite du traitement chez les patients n'ayant pas répondu au traitement au cours de cette période. |
| Infliximab | 3mg/kg pour 3 doses.<br><br>Augmentation : 5 mg/kg après 3 doses ou à la 14$^{e}$ semaine. | 3 mg/kg administrée par perfusion intraveineuse, suivie de doses supplémentaires de 3 mg/kg, 2 et 6 semaines après la première perfusion, puis toutes les 8 semaines par la suite.<br><br>Augmentation : En cas de réponse insatisfaisante, il est possible d'augmenter la dose jusqu'à 10 mg/kg et/ou de traiter le patient aussi souvent que toutes les 4 semaines. On ignore la durée de traitement nécessaire à l'obtention d'une réponse après l'augmentation de la dose. Toutefois, les monographies de produits rapportent que des doses plus élevées d'infliximab ont été associées à une proportion légèrement plus importante de patients présentant des événements indésirables (97 % pour la dose de 3 mg/kg administrée toutes les 8 semaines vs 100 % pour la dose de 10 mg/kg administrée toutes les 4 semaines), y compris des infections (84 % pour la dose de 3 mg/kg administrée toutes les 8 semaines vs 91 % pour la dose de 10 mg/kg administrée toutes les 4 semaines). |
| Rituximab | Autorisation initiale : Un traitement est composé de 2 perfusions de 1 000 mg | Posologie : 1000 mg par perfusion i.v., suivie d'une deuxième perfusion i.v. de 1000 mg, 2 semaines plus tard. |

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| | chacune.<br><br>Renouvellement : Les demandes de poursuite du traitement sont autorisées pour une période minimale de 12 mois et pour un maximum de 2 traitements. | Retraitement : Le besoin de traitements supplémentaires doit être évalué 24 semaines après le dernier traitement, selon l'activité résiduelle de la maladie ou l'obtention d'un score DAS28-vitesse de sédimentation dépassant de nouveau 2,6 (traitement jusqu'à la rémission). Il faut attendre au moins 16 semaines après l'administration d'un traitement pour amorcer un traitement supplémentaire. |
| Abatacept | Posologie par voie intraveineuse : Les autorisations sont données à raison de 10 mg/kg aux 2 semaines pour 3 doses, puis à 10 mg/kg toutes les 4 semaines.<br><br>Posologie par voie sous-cutanée : Les autorisations sont données à raison de 125 mg par semaine. | Posologie par voie intraveineuse : perfusion intraveineuse de 30 minutes, à la dose, qui est déterminée en fonction du poids : < 60 kg, 500 mg; de 60 à 100 kg, 750 mg et > 100 kg, 1 g. Après la première perfusion, ORENCIA devrait être administré deux et quatre semaines plus tard, et toutes les quatre semaines par la suite.<br><br>Posologie par voie sous-cutanée : 125 mg, une fois par semaine. |
| Sarilumab | Dose maximale de 200 mg à toutes les 2 semaines. | 200 mg une fois toutes les 2 semaines par injection sous-cutanée.<br><br>Ajustement posologique : Une diminution de la dose de 200 à 150 mg une fois toutes les 2 semaines est recommandée pour la prise en charge de la neutropénie et de la thrombocytopénie et en cas de hausse des enzymes hépatiques.<br><br>Arrêt : Il faut reconsidérer soigneusement la décision de continuer le traitement au-delà de 16 semaines chez un patient qui n'y répond pas pendant cette période. Si un patient contracte une infection grave, interrompre le traitement jusqu'à ce que l'infection soit maîtrisée. |
| Tocilizumab | Posologie par voie intraveineuse : Dose maximale de 8 mg/kg à toutes les 4 semaines.<br><br>Posologie par voie sous-cutanée : 162 mg par semaine. | Posologie par voie intraveineuse : 4 mg/kg suivis d'une augmentation à 8 mg/kg selon la réponse clinique, administrés une fois toutes les 4 semaines en perfusion intraveineuse durant 1 heure. Chez les patients pesant plus de 100 kg, il n'est pas recommandé d'administrer des doses supérieures à 800 mg par perfusion.<br><br>Posologie par voie sous-cutanée : |

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| | | Patients pesant moins de 100 kg : Dose initiale de 162 mg administrée par voie sous-cutanée toutes les deux semaines, puis passage à une administration hebdomadaire en fonction de la réponse clinique.<br><br>Patients pesant 100 kg ou plus : Dose hebdomadaire de 162 mg.<br><br>Arrêt : Le maintien du traitement au-delà de 16 semaines doit être soigneusement envisagé chez un patient qui n'a pas répondu au traitement dans ce délai.<br><br>Si un patient présente une infection grave, il faut arrêter l'administration jusqu'à ce que l'infection soit maîtrisée. |

**Tableau D-5 Information extraite des critères de remboursement du Québec et des monographies de produits pour la spondylarthrite ankylosante chez l'adulte**

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Adalimumab | Maximum de 40 mg aux 2 semaines. | 40 mg toutes les 2 semaines administrés en une seule dose par injection sous-cutanée. |
| Étanercept | Maximum de 50 mg par semaine. | 50 mg par semaine.<br><br>La dose de 50 mg doit être administrée en une seule injection sous-cutanée. La dose de 50 mg peut également être administrée en deux injections sous-cutanées de 25 mg auquel cas, les deux injections doivent être données soit une fois par semaine le même jour ou à trois ou quatre jours d'écart.<br><br>Augmentation : Comme une étude portant sur l'administration de 50 mg d'étanercept deux fois par semaine à des patients atteints de polyarthrite rhumatoïde semble indiquer une incidence plus élevée d'effets indésirables avec des taux de réponse sont similaires, les posologies supérieures à 50 mg par semaine ne sont pas recommandées. |
| Infliximab | Maximum de 5 mg/kg aux semaines 0, 2, 6 puis aux 6 à 8 semaines. | 5 mg/kg administrée par perfusion intraveineuse, suivie de doses supplémentaires de 5 mg/kg, 2 et 6 semaines après la première perfusion, puis toutes les 6 à 8 semaines par la suite. |
| Certolizumab pegol | 400 mg aux semaines 0, 2 et 4, suivies de 200 mg toutes les 2 semaines ou de 400 mg toutes les 4 semaines. | Induction : 400 mg aux semaines 0, 2 et 4, puis 200 mg toutes les 2 semaines ou 400 mg toutes les 4 semaines |
| Golimumab | 50 mg par mois. | Posologie par voie sous-cutanée : 50 mg, une fois par mois, à la même date chaque mois.<br><br>Posologie par voie intraveineuse : 2 mg/kg administré en une perfusion intraveineuse de 30 minutes aux semaines 0 et 4, et toutes les 8 semaines par la suite.<br><br>Augmentation : La monographie de Simponi$^{MC}$ souligne que les données tirées des études cliniques sur la polyarthrite rhumatoïde semblent indiquer que l'efficacité du golimumab ne s'accroît pas à des doses supérieures à 50 mg. |

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| | | Arrêt : Les données disponibles provenant des études cliniques suggèrent que la réponse clinique est généralement atteinte dans les 14 à 16 semaines de traitement (après 4 doses). Il importe de bien réfléchir à la poursuite du traitement chez les patients n'ayant pas répondu au traitement au cours de cette période. |

**Tableau D-6 Information extraite des critères de remboursement du Québec et des monographies de produits pour l'arthrite psoriasique chez l'adulte**

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Adalimumab | 40 mg aux 2 semaines | 40 mg toutes les 2 semaines par injection sous-cutanée.<br><br>Les données disponibles laissent entendre qu'on obtient habituellement une réponse clinique à l'intérieur de 12 semaines de traitement. Il faut reconsidérer soigneusement la poursuite du traitement chez la personne qui ne répond pas au traitement au cours de cette période. |
| Étanercept | 50 mg par semaine. | 50 mg par semaine.<br><br>La dose de 50 mg doit être administrée en une seule injection sous-cutanée. La dose de 50 mg peut également être administrée en deux injections sous-cutanées de 25 mg auquel cas, les deux injections doivent être données soit une fois par semaine le même jour ou à trois ou quatre jours d'écart.<br><br>Augmentation : Comme une étude portant sur l'administration de 50 mg d'étanercept deux fois par semaine à des patients atteints de polyarthrite rhumatoïde semble indiquer une incidence plus élevée d'effets indésirables avec des taux de réponse sont similaires, les posologies supérieures à 50 mg par semaine ne sont pas recommandées. |
| Infliximab | Maximum de 5 mg/kg aux semaines 0, 2, 6 puis aux 6 à 8 semaines. | 5 mg/kg administrée par perfusion intraveineuse, aux semaines 0, 2 et 6, puis toutes les 8 semaines par la suite. Si un patient ne répond pas au traitement après 24 semaines, aucune autre perfusion ne doit être administrée. |
| Certolizumab pegol | 400 mg aux semaines 0, 2 et 4, suivies de 200 mg toutes les 2 semaines ou de 400 mg toutes les 4 semaines. | Dose d'attaque: La dose d'attaque recommandée chez l'adulte est de 400 mg (2 injections sous-cutanées à 200 mg) au départ (semaine 0), la semaine 2 et la semaine 4.<br><br>Dose d'entretien : Après la dose d'attaque, la dose d'entretien recommandée chez l'adulte atteint de polyarthrite rhumatoïde est de 200 mg toutes les 2 semaines. On peut aussi envisager de prescrire le certolizumab à 400 mg toutes les 4 semaines. |

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Golimumab | Posologie par voie sous-cutanée : 50 mg par mois. | Posologie par voie sous-cutanée : 50 mg, une fois par mois.<br><br>Les données disponibles provenant des études cliniques suggèrent que la réponse clinique est généralement atteinte dans les 14 à 16 semaines de traitement (après 4 doses). Il importe de bien réfléchir à la poursuite du traitement chez les patients n'ayant pas répondu au traitement au cours de cette période. Les données tirées des études cliniques sur le rhumatisme psoriasique semblent indiquer que l'efficacité du golimumab ne s'accroît pas à des doses supérieures à 50 mg.<br><br>Posologie par voie intraveineuse : Une dose de 2 mg/kg administrée en une perfusion intraveineuse de 30 minutes aux semaines 0 et 4, et toutes les 8 semaines par la suite. |
| Ustékinumab | 45 mg aux semaines 0 et 4 puis toutes les 12 semaines. Une dose de 90 mg peut être autorisée pour les personnes dont le poids corporel est supérieur à 100 kg. | 45 mg, administrée aux semaines 0 et 4 et toutes les 12 semaines par la suite.<br><br>Augmentation : Les patients dont le poids corporel est supérieur à 100 kg peuvent recevoir une dose de 90 mg. |
| Sécukinumab | Maximum de 300 mg aux semaines 0, 1, 2, 3 et 4, puis à tous les mois. | La dose recommandée est de 150 mg administrés par injection sous-cutanée, initialement aux semaines 0, 1, 2, 3 et 4 et par la suite sous forme de traitement d'entretien mensuel.<br><br>Augmentation : Il faut envisager d'administrer la dose de 300 mg à tout patient qui n'a pas répondu de manière satisfaisante à un traitement par un anti-TNF-alpha ou dont le rhumatisme psoriasique a continué à évoluer malgré la prise d'un tel traitement |
| Ixékizumab | 160 mg à la semaine 0, suivies de 80 mg toutes les 4 semaines. | 160 mg par injection sous-cutanée (2 injections de 80 mg) au départ (semaine 0), puis de 80 mg, toutes les 4 semaines. |

**Tableau D-7 Information extraite des critères de remboursement du Québec et des monographies de produits pour l'arthrite juvénile idiopathique**

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Abatacept | 10 mg/kg aux 2 semaines pour 3 doses, puis toutes les 4 semaines. | < 75 kg : 10 mg/kg, calculée en fonction du poids du patient à chaque administration. ≥75 kg : dose pour adultes en prenant soin de ne pas dépasser une dose maximale de 1000 mg. Administration toutes les deux à quatre semaines plus tard, puis toutes les quatre semaines par la suite. |
| Adalimumab | 20 mg toutes les 2 semaines pour les enfants dont le poids est supérieur à 10 kg mais inférieur à 30 kg.<br><br>40 mg toutes les 2 semaines pour les personnes dont le poids est supérieur à 30 kg. | 10 kg à 30 kg : 20 mg toutes les 2 semaines. Une posologie de 10 mg toutes les 2 semaines, peut être envisagée pour les personnes pesant de 10 à moins de 15 kg.<br><br>≥ 30 kg : 40 mg toutes les 2 semaines. Les données disponibles laissent entendre qu'on obtient habituellement une réponse clinique à l'intérieur de 12 semaines de traitement. L'efficacité et l'innocuité de l'adalimumab chez les patients qui n'ont pas obtenu de réponse après 16 semaines de traitement n'ont pas été établies. |
| Étanercept | 0,8 mg/kg (dose maximale de 50 mg) par semaine. | 0,8 mg/kg/semaine (maximum de 50 mg par semaine). |
| Infliximab | 3 mg/kg pour 3 doses.<br><br>Augmentation : 5mg/kg après 3 doses ou à la 14e semaine. | 3 mg/kg administrée par perfusion intraveineuse, suivie de doses supplémentaires de 3 mg/kg, 2 et 6 semaines après la première perfusion, puis toutes les 8 semaines par la suite.<br><br>Augmentation : En cas de réponse insatisfaisante, il est possible d'augmenter la dose jusqu'à 10 mg/kg et/ou de traiter le patient aussi souvent que toutes les 4 semaines. On ignore la durée de traitement nécessaire à l'obtention d'une réponse après l'augmentation de la dose. Toutefois, des doses plus élevées d'infliximab ont été associées à une proportion légèrement plus importante de patients présentant des événements indésirables (97 % pour la dose de 3 mg/kg administrée toutes les 8 semaines vs 100 % pour la dose de 10 mg/kg administrée toutes les 4 semaines), y compris des infections (84 % pour la dose de 3 mg/kg administrée toutes les 8 semaines vs 91 % pour la dose de 10 mg/kg administrée toutes les 4 semaines). |

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Tocilizumab | AJI systémique : 12 mg/kg toutes les 2 semaines pour les enfants de moins de 30 kg, et de 8 mg/kg toutes les 2 semaines pour les enfants de 30 kg ou plus.<br><br>AJI polyarticulaire : 10 mg/kg toutes les 4 semaines pour les enfants de moins de 30 kg, et 8 mg/kg toutes les 4 semaines pour les enfants de 30 kg ou plus. | AJI systémique<br><br>Posologie par voie intraveineuse :<br><br>Chez les patients atteints d'AJI systémique, la dose recommandée est de 12 mg/kg lorsque le poids du patient est inférieur à 30 kg et de 8 mg/kg lorsque le poids du patient est ≥ 30 kg. L'administration se fait une fois toutes les 2 semaines par perfusion i.v. durant 1 heure.<br><br>Posologie par voie sous-cutanée : 162 mg toutes les deux semaines lorsque le poids du patient est inférieur à 30 kg et 162 mg chaque semaine lorsque le poids du patient est ≥ 30 kg.<br><br>AJI polyarticulaire<br><br>Posologie par voie intraveineuse : Chez les patients atteints d'AJIP la dose recommandée est de 10 mg/kg pour un poids inférieur à 30 kg et de 8 mg/kg pour un poids ≥ 30 kg. On l'administre une fois toutes les 4 semaines.<br><br>Posologie par voie sous-cutanée : Chez les patients atteints d'une AJIP, la dose recommandée est de 162 mg/kg une fois toutes les 3 semaines pour un poids inférieur à 30 kg et 162 mg/kg une fois toutes les 2 semaines pour un poids ≥ 30 kg.<br><br>Ajustement posologique : La dose ne change qu'à condition d'un changement pondéral constant au fil du temps.<br><br>Arrêt : Une interruption du traitement pourra être requise pour la prise en charge des anomalies dans les résultats des épreuves de laboratoire liées à la dose, notamment les élévations des enzymes hépatiques, la neutropénie et la thrombopénie. |

**Tableau D-8 Information extraite des critères de remboursement du Québec et des monographies de produits pour le psoriasis en plaques chez l'adulte**

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Adalimumab | 80 mg suivi de 40 mg aux 2 semaines. | 1 dose initiale de 80 mg administrée par voie sous-cutanée (2 injections de 40 mg), suivie de 1 dose d'entretien de 40 mg toutes les 2 semaines par voie sous-cutanée, 1 semaine après l'administration de la dose initiale.<br><br>Poursuite : Il faut reconsidérer soigneusement la poursuite du traitement au-delà de 16 semaines chez la personne qui ne répond pas au traitement après cette période. |
| Étanercept | Maximum de 50 mg 2 fois par semaine. | Induction : 50 mg deux fois par semaine (à trois ou quatre jours d'écart) pendant trois mois.<br><br>Entretien : Par la suite, il convient d'administrer la dose d'entretien de 50 mg par semaine.<br><br>Augmentation : Une dose d'entretien de 50 mg administrée deux fois par semaine s'est également révélée efficace.<br><br>La dose de 50 mg doit être administrée en une seule injection sous-cutanée. La dose de 50 mg peut également être administrée en deux injections sous-cutanées de 25 mg. Si l'étanercept est administré en deux injections de 25 mg chez les adultes ou les enfants, les deux injections doivent être données soit une fois par semaine le même jour ou à trois ou quatre jours d'écart. |
| Infliximab | 5 mg/kg aux semaines 0, 2, 6 puis aux 8 semaines. | 5 mg/kg administrée par perfusion intraveineuse, aux semaines 0, 2 et 6 semaines, puis toutes les 8 semaines par la suite.<br><br>Si la réponse au traitement n'est pas satisfaisante à la semaine 14, après les perfusions des semaines 0, 2 et 6, aucune autre perfusion ne doit être administrée. |
| Brodalumab | 210 mg aux semaines 0, 1 et 2 puis toutes les 2 semaines par la suite. | 210 mg, administrée par injection sous-cutanée aux semaines 0, 1 et 2, et par la suite de 210 mg toutes les 2 semaines. Chaque dose de 210 mg doit être administrée en une seule injection sous-cutanée à l'aide d'une seringue |

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| | | préremplie à usage unique (1,5 mL).<br><br>Arrêt : Envisager l'abandon du traitement si la réponse après 12 à 16 semaines de traitement n'est pas adéquate. En l'absence de réponse adéquate, il est improbable que la poursuite du traitement au-delà de 16 semaines donne un meilleur résultat. |
| Ixékizumab | 160 mg à la semaine 0, 80 mg aux semaines 2, 4, 6, 8, 10, 12 puis 80 mg aux 4 semaines. | 160 mg par injection sous-cutanée (2 injections de 80 mg) au départ (semaine 0), puis de 80 mg (1 injection) les deuxième, quatrième, sixième, huitième, dixième et douzième semaines (semaines 2, 4, 6, 8, 10 et 12), et enfin de 80 mg (1 injection) une fois toutes les 4 semaines. |
| Risankizumab | 150 mg (soit deux injections de 75 mg) aux semaines 0 et 4, puis toutes les 12 semaines par la suite. | 150 mg (2 injections de 75 mg) administrés par voie sous-cutanée aux semaines 0 et 4, et toutes les 12 semaines par la suite. |
| Sécukinumab | 300 mg aux semaines 0, 1, 2, 3, et 4, puis à tous les mois. | 300 mg administrés par injection sous-cutanée, initialement aux semaines 0, 1, 2, 3 et 4 par la suite sous forme de traitement d'entretien mensuel. Chaque dose de 300 mg doit être administrée en deux injections sous-cutanées de 150 mg. |
| Ustékinumab | 45 mg aux semaines 0 et 4 puis aux 12 semaines.<br><br>Une dose de 90 mg peut être autorisée pour les personnes dont le poids corporel est supérieur à 100 kg. | 45 mg, administrée aux semaines 0 et 4 puis toutes les 12 semaines par la suite.<br><br>Augmentation : Les patients dont le poids corporel est supérieur à 100 kg peuvent recevoir une dose de 90 mg. Les deux doses (45 et 90 mg) se sont avérées efficaces chez les patients pesant plus de 100 kg. Cependant, la dose de 90 mg s'est montrée efficace chez un pourcentage plus élevé de ces patients que la dose de 45 mg.<br><br>Chez les patients dont la réponse au traitement administré toutes les 12 semaines est insuffisante, il est possible d'envisager l'administration toutes les huit semaines. L'abandon du traitement devrait être envisagé chez les patients qui n'ont manifesté aucune réponse pendant 12 semaines de traitement. Après une interruption du traitement, il a été démontré que la répétition du schéma posologique aux semaines 0 et 4 et toutes les 12 semaines par la suite était efficace et sans danger. |

**Tableau D-9 Information extraite des critères de remboursement du Québec et des monographies de produits pour la dermatite atopique chronique**

| Biologique | Critère actuel (RAMQ) | Monographie |
|---|---|---|
| Dupilumab | 600 mg suivie d'une dose maximale de 300 mg toutes les 2 semaines. | 600 mg (deux injections de 300 mg), suivie d'une dose de 300 mg toutes les 2 semaines. |

**Tableau D-10 Information extraite des guides de pratique clinique pour maladie de Crohn chez l'adulte – Partie I**

| Information extraite | AGA Guidelines (Feuerstein 2021) | ECCO Guidelines (Torres 2020) | BSG Consensus Guidelines (Lamb 2019) | CAG Clinical Practice Guideline (Panaccione 2019) |
|---|---|---|---|---|
| Ajustement thérapeutique<br><br>Conduite en cas d'inefficacité | Recommandations<br><br>2B. In adult outpatients with moderate to severe CD who never responded to anti-TNFa (primary nonresponse), the AGA recommends the use of ustekinumab and suggests the use of vedolizumab over no treatment for the induction of remission. (Strong conditional recommendation, moderate low certainty of evidence).<br><br>2C. In adult outpatients with moderate to severe CD who previously responded to infliximab (secondary nonresponse), the AGA recommends the use of adalimumab or ustekinumab and suggests the use of vedolizumab over no treatment for the induction of remission. Comment: If adalimumab was the first-line drug used there is indirect evidence to suggest the option of using infliximab as a second-line agent. (Strong conditional recommendation, moderate low certainty of evidence).<br><br>Information additionnelle<br><br>Of note, the studies included in the network meta-analysis did not consistently report what proportion of patients had exposure to more than 1 TNFa antagonist, exposure to multiple different classes of | Recommandations<br><br>Recommendation 2.8. ECCO CD Treatment GL [2019]<br><br>In Crohn's disease patients in clinical remission under anti-TNF treatment, there is currently insufficient evidence to recommend for or against the use of proactive therapeutic drug monitoring to improve clinical outcomes as compared to routine care [weak recommendation, moderate-quality evidence].<br><br>Recommendation 2.9. ECCO CD Treatment GL [2019]<br><br>In Crohn's disease patients who have lost response to an anti-TNF agent, there is currently insufficient evidence to recommend for or against the use of reactive therapeutic drug monitoring to improve clinical outcomes [weak recommendation, low-quality evidence].<br><br>Information additionnelle<br><br>Data from two RCTs with a total of 395 patients with CD were used to support this recommendation (2.8). Both studies have important limitations in their study designs (107,108), which collectively have lowered the strength of our recommendation. The outcomes in | Recommandations<br><br>Good Practice Recommendation 15.<br><br>All IBD patients should be reviewed 2–4 weeks after completing loading doses of anti-TNF therapy to assess response and optimise maintenance dosing based on clinical response and measures such as serum drug and anti-drug antibody concentrations, blood inflammatory markers, faecal biomarkers or endoscopy (Agreement: 82.5%).<br><br>Good Practice Recommendation 16.<br><br>IBD patients receiving immunomodulators or biologics should have an annual review of treatment, including consideration of response and treatment continuation, optimisation or cessation (Agreement: 97.7%).<br><br>Statement 92.<br><br>We suggest that treatment options for failure of initial anti-TNF therapy (increase dose, shorten dosage interval, switch to alternative anti-TNF, or switch to different drug class) may be informed by the clinical context and by measurement of serum drug and anti-drug antibody | Recommandations<br><br>In patients with Crohn's disease who have a suboptimal response to anti-TNF induction therapy, we suggest dose intensification to achieve complete remission. GRADE: Conditional recommendation, very low-quality evidence.<br><br>In patients with Crohn's disease who lose response to anti-TNF maintenance therapy, we suggest dose optimization to recapture complete remission. GRADE: Conditional recommendation, very low-quality evidence.<br><br>We suggest that dose optimization for patients with Crohn's disease who lose response to anti-TNF therapy be informed by therapeutic drug monitoring. GRADE: Conditional recommendation, very low-quality evidence.<br><br>Information additionnelle<br><br>TDM is valuable in patients who lose response to anti-TNF therapy, and there is an association between drug concentrations and clinical outcomes. However, there is a need for more accurate descriptions of the optimal therapeutic drug ranges to help patients with CD on biologic |

| Information extraite | AGA Guidelines (Feuerstein 2021) | ECCO Guidelines (Torres 2020) | BSG Consensus Guidelines (Lamb 2019) | CAG Clinical Practice Guideline (Panaccione 2019) |
|---|---|---|---|---|
| | biologics, and reasons for failure of prior biologics (primary nonresponse vs secondary loss of response vs intolerance). In clinical practice, this information, along with information from the results of therapeutic drug monitoring (see prior AGA guideline on therapeutic drug monitoring), may affect one's decision to select one biologic over another biologic.<br><br>Importantly, use of combination therapy may be even more important in the subset of patients who have developed secondary nonresponse to TNFa antagonists.<br><br>There were no RCTs to provide data on combination therapy using vedolizumab or ustekinumab with a thiopurine or methotrexate<br><br>It is possible that the benefits of combination therapy might be achieved by therapeutic drug monitoring, using the information obtained to adjust drug dose or dosing interval. This option may provide the same benefits of combination therapy without the risk and inconvenience of adding the thiopurine or methotrexate. | both studies were clinical remission but other important issues, such as costs and immunogenicity, also need to be considered.<br><br>The prospective cohort study PANTS [Personalised Anti-TNF Therapy in Crohn's Disease Study] showed that anti-TNF failure is highly dependent on low drug concentrations and immunogenicity, and that dose intensification, especially during the induction period, may improve outcomes and treatment success (89). Therefore, the Consensus believes that large, well-powered prospective RCTs with adequate stratification of patients are still required.<br><br>Reactive TDM was compared with empirical IFX optimisation [based on clinical judgment alone] in only one randomised, controlled, single-blind, multicentre study in a cohort of 69 patients with CD with secondary IFX failure (109). There was no difference in regaining clinical response between the TDM-based group.<br><br>However, numerous studies have shown a positive association between adequate drug concentration and various clinical outcomes from clinical response to mucosal healing. Based on these observational data, recent clinical practice guidelines and a group of 25 international experts supported | concentrations (GRADE: weak recommendation, low-quality evidence. Agreement: 97.7%).<br><br>Statement 93.<br><br>We suggest that patients with secondary loss of response to anti-TNF therapy may have serum drug and antidrug antibody concentrations measured to inform appropriate changes in treatment (GRADE: weak recommendation, moderate-quality evidence. Agreement: 97.6%).<br><br>Statement 94.<br><br>We suggest that pretreatment screening and blood monitoring of therapy on vedolizumab and ustekinumab should at present follow recommendations for anti-TNF drugs due to insufficient long-term safety data at this time to recommend an alternative algorithm (GRADE: weak recommendation, very low-quality evidence. Agreement: 95.3%). | therapies achieve complete remission. These ranges may also depend on the desired outcome or disease phenotype. Prospective testing remains controversial. The studies evaluating proactive TDM have been negative but have several limitations; further studies are necessary to clarify the utility of TDM in this context. Extending beyond anti-TNF therapy, the utility of TDM with vedolizumab or ustekinumab remains poorly understood but will likely evolve. |

| Information extraite | AGA Guidelines (Feuerstein 2021) | ECCO Guidelines (Torres 2020) | BSG Consensus Guidelines (Lamb 2019) | CAG Clinical Practice Guideline (Panaccione 2019) |
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| | | the use of reactive TDM, despite recognising the very low quality of evidence (110,111). Supporting evidence comes from case-control observational studies (112,113).<br><br>Routine strategies to monitor and optimise biologic therapy in CD by a TDM approach are not supported by the available controlled evidence, although we recognise the limitations. There is no clear clinical benefit in favour of a proactive or reactive TDM approach, from the current data. However, some recent data suggest that a reactive TDM approach can result in cost savings also in the era of biosimilars (114), potentially justifying the use of such an approach where TDM is available.□TDM can at least be used to guide dose optimisation. | | |
| Adalimumab | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. |
| Infliximab | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser.<br><br>Information additionnelle<br><br>Higher infliximab doses may be beneficial for perianal fistulising | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. |

| Information extraite | AGA Guidelines (Feuerstein 2021) | ECCO Guidelines (Torres 2020) | BSG Consensus Guidelines (Lamb 2019) | CAG Clinical Practice Guideline (Panaccione 2019) |
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| | | | disease, with target levels >10µg/mL associated with better response. Drug levels vary according to the assay used, and consensus has not yet been achieved on the optimal therapeutic ranges | |
| Ustékizumab | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. |
| Védolizumab | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. |

**Tableau D-11 Information extraite des guides de pratique clinique pour maladie de Crohn chez l'adulte – Partie II**

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| Ajustement thérapeutique<br><br>Conduite en cas d'inefficacité | Recommandations<br><br>Statement 20<br><br>Patients with active inflammatory disease and therapeutic drug trough levels (suggesting pharmacodynamic failure) should ideally be switched out of class but switch within class may be effective. Level of agreement: (a) 33%, (b) 48%, (c) 19%, (d) 0%, (e) 0%. Quality of evidence: II-3. Classification of recommendation: C.<br><br>Statement 21<br><br>Patients with active inflammatory disease and undetectable drug trough levels and no antidrug antibodies (suggesting nonimmune mediated pharmacokinetic failure) should have adherence checked first followed by anti-TNF dose escalation. Level of agreement: (a) 70%, (b) 30%, (c) 0%, (d) 0%, (e) 0%. · Quality of evidence: II-3. Classification of recommendation: C. | Recommandations<br><br>In adults with active IBD treated with anti-TNF agents, the AGA suggests reactive therapeutic drug monitoring to guide treatment changes. Comment: suggested trough concentration for anti-TNF therapy are provided, for patients with active IBD on maintenance therapy. Of note, there may be a small subset of patients who may still respond by targeting higher target concentrations. Optimal trough concentrations for induction therapy are uncertain. (Conditional recommendation, very low quality of evidence).<br><br>In adult patients with quiescent IBD treated with anti-TNF agents, the AGA makes no recommendation regarding the use of routine proactive therapeutic drug monitoring. (No recommendation, knowledge gap). | Recommandations<br><br>CD Refractory to Medical Treatment<br><br>14. In case of primary nonresponse to anti-TNF, reevaluation of symptoms and change of treatment are necessary (quality of evidence, low; classification of recommendation, no specific recommendation). • Level of agreement: strongly agree 42%, agree 58%, uncertain 0%, disagree 0%, strongly disagree 0%<br><br>15. Although testing of the serum anti-TNF trough level or antibodies to anti-TNF were reported to be useful for optimizing anti-TNF therapy or identifying cause of primary nonresponse or secondary loss of response, further study is required (quality of evidence, low; classification of recommendation, weak). • Level of agreement: strongly agree 13%, agree 83%, uncertain 4%, disagree 0%, strongly disagree 0% | Recommandations<br><br>Aucune information trouvée. Voir les recommandations relatives à chaque agent biologique plus bas. | Key Findings<br><br>There is limited evidence to comparing the effectiveness of different doses of the following biologics in patients with inflammatory bowel disease (IBD): vedolizumab, adalimumab, infliximab. There were no studies on golimumab or ustekinumab identified. The sample sizes of the primary studies ranged from 33 to 778. Weekly and biweekly adalimumab doses were associated with similar clinical responses and frequencies of serious infectious adverse events. Biweekly adalimumab 40 mg or 80 mg was associated with comparable trough concentrations. The sample sizes for the trials on vedolizumab were not enough to compare the effectiveness of high and standard doses. For infliximab, dose intensification based on a multiple-criteria algorithm was similarly effective as symptom-based dose intensification in a RCT. Two of the three retrospective cohort |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | Statement 22<br><br>Patients with active inflammatory disease and undetectable drug trough levels and low titers of antidrug antibodies, which suggests immune mediated pharmacokinetic failure, should have an immunomodulator added or optimized and/or anti-TNF dose escalation. Level of agreement: (a) 64%, (b) 36%, (c) 0%, (d) 0%, (e) 0%. · Quality of evidence: II-3. Classification of recommendation: B.<br><br>Statement 23<br><br>Patients with active inflammatory disease and undetectable drug trough levels and high titers of antidrug antibodies suggest immune-mediated pharmacokinetic failure. Options include addition or optimization of an immunomodulator, and/or switching within or out of class. · Level of agreement: (a) 68%, (b) 32%, (c) 0%, (d) 0%, (e) 0%. Quality of evidence: II-2. Classification of recommendation: B. | Information additionnelle<br><br>There were no RCTs or comparative observational studies comparing a priori proactive TDM for achieving remission and thus, indirect evidence was utilized.<br><br>While initial dose optimization in a subset of patients with low trough concentrations resulted in an increase in the proportion of patients achieving clinical and biochemical remission, once the initial dose optimization was achieved with TDM, the proportion of patients achieving remission at 1 year with routine proactive TDM vs no TDM was not different (RR, 1.04; 95% CI, 0.88-1.24) (24).<br><br>Post-hoc analysis from clinical trials of induction therapy of anti-TNF drugs indicates an exposure-response relationship and patients with higher trough levels between weeks 4 and 14 were more likely to achieve remission.1 This is further supported by the data from Vande Casteele et al, (24) who noted that | 16. In patients who are intolerant or not responsive to one anti-TNF therapy, a different anti-TNF agent may be used (quality of evidence, infliximab [high], adalimumab [low]; classification of recommendation, infliximab [strong], adalimumab [weak]). • Level of agreement: strongly agree 7%, agree 80%, uncertain 13%, disagree 0%, strongly disagree 0%<br><br>Relapse during Maintenance Therapy<br><br>26. If the therapeutic efficacy of infliximab (5 mg/kg) is decreased or insufficient, shortening the interval of infusion or increasing the dose up to 10 mg/kg can be considered (quality of evidence, high; classification of recommendation, strong). • Level of agreement: strongly agree 72%, agree 28%, uncertain 0%, disagree 0%, strongly disagree 0%<br><br>27. If the therapeutic efficacy of adalimumab (40 mg bi-weekly) is decreased or insufficient, | | studies provided conflicting evidence regarding the needs for colectomy. One study found that an accelerated infliximab induction strategy reduced the need for early colectomy, while another discovered that an accelerated infliximab doses after initial standard infusion was associated with higher colectomy rates for patients with acute ulcerative colitis. In the third retrospective cohort study by Nagata et al., doubling the infliximab dose and shortening the intervals of infliximab infusion were similarly effective to achieve clinical response, compared to switching to adalimumab in the short or long run. The included guideline indicated that for those who are considered secondary non-responders, dose escalation or switching may be appropriate. No relevant cost-effectiveness studies regarding higher or more frequent versus standard dosing or switching of biologics for the treatment of inflammatory bowel disease. |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | | uniform dose optimization resulted in an increase in proportion of patients in clinical remission (from 65% pre-optimization to 88% post-optimization). While this supports the notion that early optimization of therapy based on proactive TDM testing can be helpful, the magnitude of benefit for patient-important outcomes, long-term benefit over reactive TDM, and frequency of assessments in proactive TDM are unclear.1 | weekly adalimumab administration can be considered (quality of evidence, high; classification of recommendation, strong). • Level of agreement: strongly agree 70%, agree 30%, uncertain 0%, disagree 0%, strongly disagree 0%<br><br>28. If the therapeutic efficacy is insufficient after shortening the interval of administration or increasing the dose of anti-TNF agents, switching to another anti-TNF agent can be considered (quality of evidence, high; classification of recommendation, strong). • Level of agreement: strongly agree 36%, agree 64%, uncertain 0%, disagree 0%, strongly disagree 0% | | |
| Adalimumab | Statement 18 In patients with CD and UC we recommend a steady state trough infliximab level between 3 and 7 µg/mL and adalimumab trough level between 4 and 8 µg/mL. Level of agreement: (a) 45%, (b) 41%, (c) 14%, (d) 0%, (e) 0%. Quality of evidence: II-2 · Classification of | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser.<br><br>Suggested Target Trough Concentrations When Applying Reactive Therapeutic Drug Monitoring<br><br>≥ 7.5 mg/mL. Four studies provided data on | Voir les recommandations de la section précédente sur l'optimisation du traitement. | <u>TA187 (2018)</u><br><br>The adalimumab induction treatment dose regimen for adults with severe Crohn's disease is 80 mg via subcutaneous injection, followed by 40 mg 2 weeks later. If there is a need for a more rapid response to therapy, a dose of 160 mg followed by 80 mg 2 weeks later can be used, though | For adalimumab in CD patients, high and standard doses were tried and the two RCTs confirmed the effectiveness of adalimumab at standard or higher dosing. [20,23] However, there was insufficient sample size to test the significance of the differences between two doses.[20,23] |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | recommendation: B | proportion of patients not in remission above adalimumab trough concentration >5.0 ± 1 mg/mL or 7.5 ± 1 mg/mL. On analysis of different thresholds, proportion of patients not in remission progressively decreased from 17% when using an adalimumab threshold ≥ 5.0 ± 1 mg/mL, to 10% with an adalimumab trough concentration of ≥ 7.5 ± 1 mg/mL. Different studies used different assays, and there are limited data on comparability of trough concentrations identified in different assays for adalimumab. It is unclear what proportion of patients on standard (40 mg every other week) or escalated adalimumab dosing (40 mg every week) would be able to achieve these thresholds. | | the risk of adverse events with this higher dose is greater during induction. After induction treatment the recommended dose is 40 mg every other week. This can be increased to 40 mg every week in people whose disease shows a decrease in response to treatment. According to the SPC, continued therapy should be carefully reconsidered in patients whose disease does not respond within 12 weeks of initiating treatment.<br><br><u>Electronic medicines compendium (EMC 2021)</u><br><br>The recommended Humira induction dose regimen for adult patients with moderately to severely active Crohn's disease is 80 mg at Week 0 followed by 40 mg at Week 2. In case there is a need for a more rapid response to therapy, the regimen 160 mg at Week 0 (given as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections in one day), can be used with the awareness that the risk for | |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | | | | adverse events is higher during induction.<br><br>After induction treatment, the recommended dose is 40 mg every other week via subcutaneous injection.<br><br>Some patients who experience decrease in their response to Humira 40 mg every other week may benefit from an increase in dosage to 40 mg Humira every week or 80 mg every other week.<br><br>Some patients who have not responded by Week 4 may benefit from continued maintenance therapy through Week 12. Continued therapy should be carefully reconsidered in a patient not responding within this time period. | |
| Infliximab | Statement 18 In patients with CD and UC we recommend a steady state trough infliximab level between 3 and 7 µg/mL and adalimumab trough level between 4 and 8 µg/mL. Level of agreement: (a) 45%, (b) 41%, (c) 14%, (d) 0%, (e) 0%. · Quality of evidence: II-2 · Classification of recommendation: B | Suggested Target Trough Concentrations When Applying Reactive Therapeutic Drug Monitoring<br><br>Infliximab ≥ 5 mg/mL<br><br>Six studies (929 patients) provided data on proportion of patients not in remission above predefined infliximab thresholds (1, 3, 5, 7, and | Voir les recommandations de la section précédente sur l'optimisation du traitement. | <u>TA187 (2018)</u><br><br>For severe, active Crohn's disease, infliximab is given as a 5-mg/kg intravenous infusion over a 2-hour period followed by another 5-mg/kg infusion 2 weeks after the first. If a person's disease does not respond after two doses, no additional treatment with infliximab should be given. In people whose disease | Infliximab was tested in one RCT on CD patients[21] and in two retrospective cohort studies on patients hospitalized for UC. [24,26] Dose intensification based on a multiple-criteria algorithm was similarly effective as symptom-based dose intensification in the RCT. [21] By comparing cohorts of different time periods, before 2011 or in 2011, |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | | 10 mg/mL). Based on these, proportion of patients not in remission decreased from 25% when using an infliximab threshold of ≥ 1 mg/mL, to 15% with an infliximab trough concentration of ≥ 3 mg/mL, to approximately 4% with an infliximab trough concentration of ≥ 7 mg/mL or ≥ 10 mg/mL. | | responds, infliximab regimens include maintenance treatment (another 5-mg/kg infusion at 6 weeks after the initial dose, followed by infusions every 8 weeks) or re-administration, otherwise known as episodic treatment (an infusion of 5-mg/ kg if signs and symptoms of the disease recur) in line with the marketing authorisation. In adults, dose escalation is an option for people whose disease Infliximab and adalimumab for the treatment of Crohn's disease has stopped responding. According to the SPC, continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit after dose adjustment.<br><br>For fistulising, active Crohn's disease, infliximab is given as a 5-mg/kg infusion over a 2-hour period followed by additional 5-mg/kg infusions at 2 and 6 weeks after the first. If a person's disease does not respond after three doses, no further treatment with infliximab should be given. In people whose disease responds, infliximab can | Gibson et al. found that more frequent induction of three doses of infliximab were associated with less need for colectomy.[24] Though it was not mentioned whether there were other differences in clinical practices between the two time periods. [24] In contrast, Shah et al. found that high-dose induction therapy was associated with higher 30-day colectomy.[26] These two retrospective cohort studies provided somewhat conflicting evidence. In the retrospective cohort study by Nagata et al., doubling the infliximab dose and shortening the intervals of infliximab infusion were similarly effective to achieve clinical response, compared to switching to adalimumab between weeks 4 and 48 after initial treatment. [25] The included studies were limited by small sample sizes, heterogeneity in study settings, diverse interventions, and different patient characteristics. The quality of the RCTs was fair to poor.[20-23] There was no information on allocation concealment in the RCTs.[20-23] There might not have been sufficient |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | | | | be given as maintenance treatment (5-mg/kg infusions every 8 weeks) or as re-administration treatment (5-mg/kg when signs and symptoms recur, followed by infusions of 5-mg/kg every 8 weeks). In adults, dose escalation is an option for people whose disease has stopped responding.<br><br><u>Electronic medicines compendium (EMC 2021)</u><br><br>5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion. If a patient does not respond after 2 doses, no additional treatment with infliximab should be given. Available data do not support further infliximab treatment, in patients not responding within 6 weeks of the initial infusion.<br><br>In responding patients, the alternative strategies for continued treatment are:<br><br>• Maintenance: Additional infusion of 5 mg/kg at 6 weeks after the initial dose, followed by infusions every 8 weeks or<br><br>• Re-administration: | sample sizes to detect adverse events. The three retrospective cohort studies had the limitation that outcome data were available in the medical records at the time of study.[24-26] |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | | | | Infusion of 5 mg/kg if signs and symptoms of the disease recur.<br><br>Although comparative data are lacking, limited data in patients who initially responded to 5 mg/kg but who lost response indicate that some patients may regain response with dose escalation. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit after dose adjustment. | |
| Ustékizumab | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Voir les recommandations de la section précédente sur l'optimisation du traitement. | TA456 (2017)<br><br>Ustekinumab has a marketing authorisation in the UK for treating 'adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-alpha inhibitor or have medical contraindications to such therapies:<br><br>• Patients who have not shown adequate response at 8 weeks after the first subcutaneous dose may receive a second subcutaneous dose at | There were no studies on golimumab or ustekinumab identified. |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | | | | this time.<br><br>• Patients who lose response on dosing every 12 weeks may benefit from an increase in dosing frequency to every 8 weeks.<br><br>• Patients may subsequently be dosed every 8 weeks or every 12 weeks according to clinical judgment'.<br><br>Ustekinumab is given as intravenous infusion at induction and as subcutaneous injection at maintenance:<br>1 intravenous induction treatment (dose depends on body weight and is approximately 6 mg/kg). Maintenance subcutaneous treatment at week 8 (90 mg), then every 12 weeks.<br><br><u>Electronic medicines compendium (EMC 2021)</u><br><br>STELARA treatment is to be initiated with a single intravenous dose based on body weight. The infusion solution is to be composed of the number of vials of STELARA 130 mg (approximately 6 mg/kg) as | |

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| | | | | follows:<br>≤ 55 kg : 260 mg (2 vials)<br>> 55 kg to ≤ 85 kg :<br>390 mg (3 vials)<br>> 85 kg : 520 mg (4 vials)<br><br>Subcutaneous injections<br><br>The first subcutaneous administration of 90 mg STELARA should take place at week 8 after the intravenous dose.<br>After this, dosing every 12 weeks is recommended.<br><br>Patients who have not shown adequate response at 8 weeks after the first subcutaneous dose, may receive a second subcutaneous dose at this time.<br><br>Patients who lose response on dosing every 12 weeks may benefit from an increase in dosing frequency to every 8 weeks.<br><br>Patients may subsequently be dosed every 8 weeks or every 12 weeks according to clinical judgment.<br><br>Consideration should be given to discontinuing treatment in patients who show no evidence of | |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | | | | therapeutic benefit 16 weeks after the IV induction dose or 16 weeks after switching to the 8-weekly maintenance dose.<br><br>In Crohn's disease or Ulcerative Colitis, if therapy is interrupted, resumption of treatment with subcutaneous dosing every 8 weeks is safe and effective. | |
| Védolizumab | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | <u>TA352 (2015)</u><br><br>The summary of product characteristics states that the recommended dosage of vedolizumab for treating Crohn's disease is 300 mg at 0, 2 and 6 weeks, then every 8 weeks thereafter. It further notes that people who have not shown a response may benefit from a dose at week 10. If no evidence of therapeutic benefit is seen by week 14, vedolizumab should not be continued.<br><br><u>Electronic medicines compendium (EMC 2021)</u><br><br>The recommended dose regimen of intravenous vedolizumab is 300 mg administered by intravenous infusion at 0, 2 | Three doses of vedolizumab were tested in the RCT on UC patients by Parikh et al.[22] This RCT confirmed that vedolizumab was well tolerated and verified the dose-response relationship in pharmacokinetics.[22] However, this RCT was also underpowered for effectiveness comparison.[22] |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | | | | and 6 weeks and then every 8 weeks thereafter.<br><br>Patients with Crohn's disease, who have not shown a response may benefit from a dose of intravenous vedolizumab at week 10. Therapy should be continued every 8 weeks from week 14 in responding patients. Therapy for patients with Crohn's disease should be discontinued if no evidence of therapeutic benefit is observed by week 14.<br><br>Some patients who have experienced a decrease in their response may benefit from an increase in dosing frequency to Entyvio 300 mg every 4 weeks.<br><br>Maintenance<br><br>The recommended dose regimen of subcutaneous vedolizumab as a maintenance treatment, following at least 2 intravenous infusions, is 108 mg administered by subcutaneous injection once every 2 weeks. The first subcutaneous dose should be administered in place of the next scheduled intravenous dose and every 2 weeks | |

| Information extraite | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean guidelines (Park 2017) | NICE TA187 (2018), TA456 (2017), TA352 (2015) | CADTH Rapid Response (Chao 2018) |
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| | | | | thereafter.<br><br>Insufficient data are available to determine if patients who experience a decrease in response on maintenance treatment with subcutaneous vedolizumab would benefit from an increase in dosing frequency. | |

**Tableau D-12 Information extraite des guides de pratique clinique pour la colite ulcéreuse chez l'adulte – Partie I**

| Information extraite | AGA Clinical Practice Guidelines (Feuerstein 2020) | BSG Consensus Guidelines (Lamb 2019) | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean Guidelines (Choi 2017) |
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| Ajustement thérapeutique<br><br>Conduite en cas d'inefficacité | Recommandations<br><br>2c. In hospitalized adult patients with acute severe UC being treated with infliximab, the AGA makes no recommendation on routine use of intensive vs standard infliximab dosing. (No recommendation, knowledge gap).<br><br>Information additionnelle<br><br>Therapeutic drug monitoring to guide the use of biologic therapy has been addressed in separate AGA guidelines (Papamichael 2019). | Recommandations<br><br>Good Practice Recommendation 15.<br><br>All IBD patients should be reviewed 2–4 weeks after completing loading doses of anti-TNF therapy to assess response and optimise maintenance dosing based on clinical response and measures such as serum drug and anti-drug antibody concentrations, blood inflammatory markers, faecal biomarkers or endoscopy (Agreement: 82.5%).<br><br>Good Practice Recommendation 16.<br><br>IBD patients receiving immunomodulators or biologics should have an annual review of treatment, including consideration of response and treatment continuation, optimisation or cessation (Agreement: 97.7%).<br><br>Statement 92.<br><br>We suggest that treatment options for failure of initial anti-TNF therapy (increase | Recommandations<br><br>Statement 20<br><br>Patients with active inflammatory disease and therapeutic drug trough levels (suggesting pharmacodynamic failure) should ideally be switched out of class but switch within class may be effective. Level of agreement: (a) 33%, (b) 48%, (c) 19%, (d) 0%, (e) 0%. Quality of evidence: II-3. Classification of recommendation: C.<br><br>Statement 21<br><br>Patients with active inflammatory disease and undetectable drug trough levels and no antidrug antibodies (suggesting nonimmune mediated pharmacokinetic failure) should have adherence checked first followed by anti-TNF dose escalation. Level of agreement: (a) 70%, (b) 30%, (c) 0%, (d) 0%, (e) 0%. · Quality of evidence: II-3. Classification of recommendation: C. | Recommandations<br><br>In adults with active IBD treated with anti-TNF agents, the AGA suggests reactive therapeutic drug monitoring to guide treatment changes. Comment: suggested trough concentration for anti-TNF therapy are provided, for patients with active IBD on maintenance therapy. Of note, there may be a small subset of patients who may still respond by targeting higher target concentrations. Optimal trough concentrations for induction therapy are uncertain. (Conditional recommendation, very low quality of evidence).<br><br>In adult patients with quiescent IBD treated with anti-TNF agents, the AGA makes no recommendation regarding the use of routine proactive therapeutic drug monitoring. (No recommendation, knowledge gap). | Recommandations<br><br>23. Evaluation of treatment response is recommended after 8−12 weeks of anti-TNF therapy to determine the need to modify therapy (quality of evidence, low; classification of recommendation, strong). • Level of agreement: strongly agree 42.6%, agree 57.5%, uncertain 0%, disagree 0%, strongly disagree 0%<br><br>24. Anti-TNF dose escalation is recommended for remission induction when no sufficient response is achieved. Shortening the infusion interval of infliximab or elevating the dose to 10 mg/kg is recommended. The injection frequency of adalimumab is shortened to 1 week (quality of evidence, very low; classification of recommendation, strong). • Level of agreement: strongly agree 25.6%, agree 58.1%, uncertain 16.3%, disagree 0%, strongly disagree 0%. |

| Information extraite | AGA Clinical Practice Guidelines (Feuerstein 2020) | BSG Consensus Guidelines (Lamb 2019) | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean Guidelines (Choi 2017) |
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| | | dose, shorten dosage interval, switch to alternative anti-TNF, or switch to different drug class) may be informed by the clinical context and by measurement of serum drug and anti-drug antibody concentrations (GRADE: weak recommendation, low-quality evidence. Agreement: 97.7%).<br><br>Statement 93.<br><br>We suggest that patients with secondary loss of response to anti-TNF therapy may have serum drug and antidrug antibody concentrations measured to inform appropriate changes in treatment (GRADE: weak recommendation, moderate-quality evidence. Agreement: 97.6%).<br><br>Statement 94.<br><br>We suggest that pretreatment screening and blood monitoring of therapy on vedolizumab and ustekinumab should at present follow recommendations for anti-TNF drugs due to insufficient long-term safety data at this time to | Statement 22<br><br>Patients with active inflammatory disease and undetectable drug trough levels and low titers of antidrug antibodies, which suggests immune mediated pharmacokinetic failure, should have an immunomodulator added or optimized and/or anti-TNF dose escalation. Level of agreement: (a) 64%, (b) 36%, (c) 0%, (d) 0%, (e) 0%. · Quality of evidence: II-3. Classification of recommendation: B.<br><br>Statement 23<br><br>Patients with active inflammatory disease and undetectable drug trough levels and high titers of antidrug antibodies suggest immune-mediated pharmacokinetic failure. Options include addition or optimization of an immunomodulator, and/or switching within or out of class. · Level of agreement: (a) 68%, (b) 32%, (c) 0%, (d) 0%, (e) 0%. Quality of evidence: II-2. Classification of recommendation: B. | Information additionnelle<br><br>There were no RCTs or comparative observational studies comparing a priori proactive TDM for achieving remission and thus, indirect evidence was utilized.<br><br>While initial dose optimization in a subset of patients with low trough concentrations resulted in an increase in the proportion of patients achieving clinical and biochemical remission, once the initial dose optimization was achieved with TDM, the proportion of patients achieving remission at 1 year with routine proactive TDM vs no TDM was not different (RR, 1.04; 95% CI, 0.88-1.24) (24).<br><br>Post-hoc analysis from clinical trials of induction therapy of anti-TNF drugs indicates an exposure-response relationship and patients with higher trough levels between weeks 4 and 14 were more likely to achieve remission.1 This is further supported by the data from Vande Casteele et al, (24) who noted that | 25. In patients who have primary nonresponse in remission induction with anti-TNF, vedolizumab treatment may be more effective than switching to another anti-TNF agent (quality of evidence, very low; classification of recommendation, weak). • Level of agreement: strongly agree 2.0%, agree 73.5%, uncertain 20.4%, disagree 4.1%, strongly disagree 0%.<br><br>26. In patients with loss of secondary response to anti-TNF, different types of anti-TNF agents or vedolizumab treatment is recommended based on therapeutic drug monitoring (quality of evidence, very low; classification of recommendation, strong). • Level of agreement: strongly agree 17.4%, agree 73.9%, uncertain 6.5%, disagree 2.2%, strongly disagree 0%.<br><br>27. Vedolizumab is considered for remission induction when moderate to severe UC fails to respond to corticosteroids, thiopurine, or anti-TNF (quality of evidence, |

| Information extraite | AGA Clinical Practice Guidelines (Feuerstein 2020) | BSG Consensus Guidelines (Lamb 2019) | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean Guidelines (Choi 2017) |
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| | | recommend an alternative algorithm (GRADE: weak recommendation, very low-quality evidence. Agreement: 95.3%). | | uniform dose optimization resulted in an increase in proportion of patients in clinical remission (from 65% pre-optimization to 88% post-optimization). While this supports the notion that early optimization of therapy based on proactive TDM testing can be helpful, the magnitude of benefit for patient-important outcomes, long-term benefit over reactive TDM, and frequency of assessments in proactive TDM are unclear.1 | moderate; classification of recommendation, strong). • Level of agreement: strongly agree 4.4%, agree 80.4%, uncertain 10.9%, disagree 4.4%, strongly disagree 0%.<br><br>28. Evaluation of treatment response is recommended after 8−14 weeks of vedolizumab therapy to determine the need to modify therapy (quality of evidence, very low; classification of recommendation, strong). • Level of agreement: strongly agree 26.7%, agree 71.1%, uncertain 2.2%, disagree 0%, strongly disagree 0%. |
| Adalimumab | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Statement 18 In patients with CD and UC we recommend a steady state trough infliximab level between 3 and 7 µg/mL and adalimumab trough level between 4 and 8 µg/mL. Level of agreement: (a) 45%, (b) 41%, (c) 14%, (d) 0%, (e) 0%. · Quality of evidence: II-2 · Classification of recommendation: B | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser.<br><br>Suggested Target Trough Concentrations When Applying Reactive Therapeutic Drug Monitoring<br><br>≥ 7.5 mg/mL. Four studies provided data on proportion of patients not in remission above adalimumab trough concentration >5.0 ± 1 mg/mL or 7.5 ± 1 mg/mL. | |

| Information extraite | AGA Clinical Practice Guidelines (Feuerstein 2020) | BSG Consensus Guidelines (Lamb 2019) | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean Guidelines (Choi 2017) |
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| | | | | On analysis of different thresholds, proportion of patients not in remission progressively decreased from 17% when using an adalimumab threshold ≥ 5.0 ± 1 mg/mL, to 10% with an adalimumab trough concentration of ≥ 7.5 ± 1 mg/mL. Different studies used different assays, and there are limited data on comparability of trough concentrations identified in different assays for adalimumab. It is unclear what proportion of patients on standard (40 mg every other week) or escalated adalimumab dosing (40 mg every week) would be able to achieve these thresholds. | |
| Infliximab | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Statement 19.<br><br>We suggest that patients treated with infliximab for acute severe ulcerative colitis (ASUC) who have not responded sufficiently to a 5mg/kg dose 3–5 days after first infusion should be treated with an accelerated induction regimen after colorectal surgical review to determine whether emergency colectomy is required (GRADE: weak | Statement 18<br><br>In patients with CD and UC we recommend a steady state trough infliximab level between 3 and 7 µg/mL and adalimumab trough level between 4 and 8 µg/mL. Level of agreement: (a) 45%, (b) 41%, (c) 14%, (d) 0%, (e) 0%. · Quality of evidence: II-2 · Classification of recommendation: B | Suggested Target Trough Concentrations When Applying Reactive Therapeutic Drug Monitoring<br><br>Infliximab ≥ 5 mg/mL<br><br>Six studies (929 patients) provided data on proportion of patients not in remission above predefined infliximab thresholds (1, 3, 5, 7, and 10 mg/mL). Based on these, proportion of patients not in remission | |

| Information extraite | AGA Clinical Practice Guidelines (Feuerstein 2020) | BSG Consensus Guidelines (Lamb 2019) | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean Guidelines (Choi 2017) |
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| | | recommendation, low-quality evidence. Agreement: 95.7%).<br><br>Information additionnelle<br><br>Patients treated with infliximab who are not responding sufficiently to a 5mg/kg dose after 3–5 days can be treated with an early repeat infusion, particularly in those with a low albumin (below 35g/L). Some clinicians use an initial 10mg/kg dose as salvage therapy but there is as yet insufficient data to demonstrate the value of this in comparison to a 5mg/kg dose. Optimal timing and dose (5mg/kg or 10mg/kg) are as yet unclear. Accelerated dosing should only be given after colorectal surgical review, with agreement that colectomy is not required imminently | | decreased from 25% when using an infliximab threshold of ≥ 1 mg/mL, to 15% with an infliximab trough concentration of ≥ 3 mg/mL, to approximately 4% with an infliximab trough concentration of ≥ 7 mg/mL or ≥ 10 mg/mL. | |
| Ustékinumab | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | |

| Information extraite | AGA Clinical Practice Guidelines (Feuerstein 2020) | BSG Consensus Guidelines (Lamb 2019) | Best practices in Asia (Ooi 2019) | AGA Guideline on TDM in IBD (Feuerstein 2017) | Second Korean Guidelines (Choi 2017) |
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| Védolizumab | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | |

## Tableau D-13 Information extraite des guides de pratique clinique pour la colite ulcéreuse chez l'adulte – Partie II

| Information extraite | CADTH Rapid Response (Chao 2018) | NICE TA329 (2018), TA342 (2015), TA633 (2020) |
|---|---|---|
| Ajustement thérapeutique<br>Conduite en cas d'inefficacité | Key Findings<br><br>There is limited evidence to comparing the effectiveness of different doses of the following biologics in patients with inflammatory bowel disease (IBD): vedolizumab, adalimumab, infliximab. There were no studies on golimumab or ustekinumab identified. The sample sizes of the primary studies ranged from 33 to 778. Weekly and biweekly adalimumab doses were associated with similar clinical responses and frequencies of serious infectious adverse events. Biweekly adalimumab 40 mg or 80 mg was associated with comparable trough concentrations. The sample sizes for the trials on vedolizumab were not enough to compare the effectiveness of high and standard doses. For infliximab, dose intensification based on a multiple-criteria algorithm was similarly effective as symptom-based dose intensification in a RCT. Two of the three retrospective cohort studies provided conflicting evidence regarding the needs for colectomy. One study found that an accelerated infliximab induction strategy reduced the need for early colectomy, while another discovered that an accelerated infliximab doses after initial standard infusion was associated with higher colectomy rates for patients with acute ulcerative colitis. In the third retrospective cohort study by Nagata et al., doubling the infliximab dose and shortening the intervals of infliximab infusion were similarly effective to achieve clinical response, compared to switching to adalimumab in the short or long run. The included guideline indicated that for those who are considered secondary non-responders, dose escalation or switching may be appropriate. No relevant cost-effectiveness studies regarding higher or more frequent versus standard dosing or switching of biologics for the treatment of inflammatory bowel disease. | Recommandations<br><br>Aucune information trouvée. Voir les recommandations relatives à chaque agent biologique plus bas. |
| Adalimumab | For adalimumab in CD patients, high and standard doses were tried and the two RCTs confirmed the effectiveness of adalimumab at standard or higher dosing. [20,23] However, there was insufficient sample size to test the significance of the differences between two doses.[20,23] | TA329 (2018)<br><br>Adalimumab is administered by subcutaneous injection. The recommended induction dose regimen is 160 mg at week 0 and 80 mg at week 2. After induction treatment, the recommended dose is 40 mg every other week. The summary of product characteristics recommends that therapy should be stopped in patients whose disease failed to respond to adalimumab within 2 to 8 weeks after starting treatment. |

| Information extraite | CADTH Rapid Response (Chao 2018) | NICE TA329 (2018), TA342 (2015), TA633 (2020) |
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| | | Electronic medicines compendium (EMC 2021)<br><br>he recommended Humira induction dose regimen for adult patients with moderate to severe ulcerative colitis is 160 mg at Week 0 (given as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days) and 80 mg at Week 2 (given as two 40 mg injections in one day). After induction treatment, the recommended dose is 40 mg every other week via subcutaneous injection.<br><br>Some patients who experience decrease in their response to 40 mg every other week may benefit from an increase in dosage to 40 mg Humira every week or 80 mg every other week.<br><br>Available data suggest that clinical response is usually achieved within 2-8 weeks of treatment. Humira therapy should not be continued in patients failing to respond within this time period. |
| Infliximab | Infliximab was tested in one RCT on CD patients[21] and in two retrospective cohort studies on patients hospitalized for UC. [24,26] Dose intensification based on a multiple-criteria algorithm was similarly effective as symptom-based dose intensification in the RCT. [21] By comparing cohorts of different time periods, before 2011 or in 2011, Gibson et al. found that more frequent induction of three doses of infliximab were associated with less need for colectomy.[24] Though it was not mentioned whether there were other differences in clinical practices between the two time periods. [24] In contrast, Shah et al. found that high-dose induction therapy was associated with higher 30-day colectomy.[26] These two retrospective cohort studies provided somewhat conflicting evidence. In the retrospective cohort study by Nagata et al., doubling the infliximab dose and shortening the intervals of infliximab infusion were similarly effective to achieve clinical response, compared to switching to adalimumab between weeks 4 and 48 after initial treatment. [25] The included studies were limited by small sample sizes, heterogeneity in study settings, diverse interventions, and different patient characteristics. The quality of the RCTs was fair to poor.[20-23] There was no information on allocation concealment in the RCTs.[20-23] There might not have been sufficient sample sizes to detect adverse events. The three retrospective cohort studies had the limitation that outcome data were available in the medical records at the time of study.[24-26] | TA329 (2015)<br><br>Infliximab is administered by intravenous infusion. For both the adult and paediatric populations, the recommended dose of infliximab is 5 mg/kg at weeks 0, 2 and 6, then at every 8 weeks. The summary of product characteristics recommends that continued infliximab therapy should be carefully reconsidered in adults who do not benefit within the first 14 weeks of treatment.<br><br>Electronic medicines compendium (EMC 2021)<br><br>5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.<br><br>Available data suggest that the clinical response is usually achieved within 14 weeks of treatment, i.e. three doses. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within this time period. |

| Information extraite | CADTH Rapid Response (Chao 2018) | NICE TA329 (2018), TA342 (2015), TA633 (2020) |
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| Ustékinumab | There were no studies on golimumab or ustekinumab identified. | TA633 (2020)<br><br>Ustekinumab is recommended as an option for treating moderately to severely active ulcerative colitis in adults when conventional therapy or a biological agent cannot be tolerated, or the disease has responded inadequately or lost response to treatment, only if:<br><br>• a tumour necrosis factor-alpha inhibitor has failed (that is the disease has responded inadequately or has lost response to treatment) or<br>• a tumour necrosis factor-alpha inhibitor cannot be tolerated or is not suitable, and<br>• the company provides ustekinumab at the same price or lower than that agreed with the Commercials Medicines Unit.<br><br>The dosage schedule is available in the summary of product characteristics.<br><br>(Electronic medicines compendium (EMC) (2021)) :<br><br>STELARA treatment is to be initiated with a single intravenous dose based on body weight. The infusion solution is to be composed of the number of vials of STELARA 130 mg as specified in Table 1 (approximately 6 mg/kg).<br><br>Table 1 Initial intravenous dosing of STELARA<br><br>≤ 55 kg : 260 mg (2 vials)<br><br>> 55 kg to ≤ 85 kg : 390 mg (3 vials)<br><br>> 85 kg : 520 mg (4 vials)<br><br>The first subcutaneous dose should be given at week 8 following the intravenous dose. For the posology of the subsequent subcutaneous dosing regimen, see section 4.2 of the STELARA solution for injection (vial) and solution for injection in pre-filled syringe SmPC. |

| Information extraite | CADTH Rapid Response (Chao 2018) | NICE TA329 (2018), TA342 (2015), TA633 (2020) |
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| | | The first subcutaneous administration of 90 mg STELARA should take place at week 8 after the intravenous dose. After this, dosing every 12 weeks is recommended.<br><br>Patients who have not shown adequate response at 8 weeks after the first subcutaneous dose, may receive a second subcutaneous dose at this time (see section 5.1).<br><br>Patients who lose response on dosing every 12 weeks may benefit from an increase in dosing frequency to every 8 weeks (see section 5.1, section 5.2).<br><br>Patients may subsequently be dosed every 8 weeks or every 12 weeks according to clinical judgment (see section 5.1).<br><br>Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit 16 weeks after the IV induction dose or 16 weeks after switching to the 8-weekly maintenance dose. |
| Védolizumab | Three doses of vedolizumab were tested in the RCT on UC patients by Parikh et al.[22] This RCT confirmed that vedolizumab was well tolerated and verified the dose-response relationship in pharmacokinetics.[22] However, this RCT was also underpowered for effectiveness comparison.[22] | TA342 (2015)<br><br>The recommended dosage of vedolizumab is 300 mg given by intravenous infusion at 0, 2 and 6 weeks and then every 8 weeks thereafter. Continued therapy for people with ulcerative colitis should be carefully reconsidered if no evidence of therapeutic benefit is observed by week 10.<br><br>Electronic medicines compendium (EMC) (2021) :<br><br>The recommended dose regimen of intravenous vedolizumab is 300 mg administered by intravenous infusion at 0, 2 and 6 weeks and then every 8 weeks thereafter.<br><br>Therapy for patients with ulcerative colitis should be discontinued if no evidence of therapeutic benefit is observed by week 10.<br><br>Some patients who have experienced a decrease in their response may benefit from an increase in dosing frequency to intravenous vedolizumab 300 mg every 4 weeks. |

| Information extraite | CADTH Rapid Response (Chao 2018) | NICE TA329 (2018), TA342 (2015), TA633 (2020) |
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| | | Retreatment<br><br>If therapy is interrupted and there is a need to restart treatment with intravenous vedolizumab dosing at every 4 weeks may be considered. The treatment interruption period in clinical trials extended up to 1 year. Efficacy was regained with no evident increase in adverse reactions or infusion-related reactions during retreatment with vedolizumab.<br><br>Maintenance treatment<br><br>The recommended dose regimen of subcutaneous vedolizumab as a maintenance treatment, following at least 2 intravenous infusions, is 108 mg administered by subcutaneous injection once every 2 weeks. The first subcutaneous dose should be administered in place of the next scheduled intravenous dose and every 2 weeks thereafter.<br><br>Insufficient data are available to determine if patients who experience a decrease in response on maintenance treatment with subcutaneous vedolizumab would benefit from an increase in dosing frequency. |

**Tableau D-14 Information extraite des guides de pratique clinique pour la maladie de Crohn pédiatrique**

| Information extraite | ECCO-ESPGHAN Guideline Update (Van Rheenen 2021) | CAG Clinical Practice Guideline (Mack 2019) | NICE TA187 (2018) |
|---|---|---|---|
| Ajustement thérapeutique<br><br>Conduite en cas d'inefficacité | Recommandations<br><br>In patients with luminal CD in clinical remission, a significant rise of faecal calprotectin should trigger further investigations and consideration of treatment escalation. Level of Evidence: 3 \| Agreement: 92%.<br><br>In patients on anti-TNF agents, early proactive therapeutic drug monitoring [TDM] followed by dose optimisation is recommended. Level of Evidence: 2 \| Agreement: 87.5%.<br><br>In patients with active CD who are treated with anti-TNF agents, it is recommended to use TDM to guide treatment changes over empirically escalating the dose or switching therapies. Level of Evidence: 3 \| Agreement: 96%<br><br>Information additionnelle<br><br>Anti-TNF agents are highly effective drugs for the treatment of paediatric CD, but 10–30% of patients do not respond to induction therapy [ie., primary non-responders] and approximately 50% of initial responders lose response at a later time [ie, secondary LOR]. Both primary non-response and secondary LOR in anti-TNF treated patients commonly result from either low trough concentration or high ADA titre or both.<br><br>Proactive TDM is of benefit when performed early in the course of treatment [post-induction]. We recommend that paediatric patients with CD treated with adalimumab have their first proactive TDM just before the third injection [ie, 4 weeks after the first dose]. | Recommandations<br><br>In patients with CD who have a suboptimal clinical response to anti-TNF induction therapy or loss of response to maintenance therapy, we suggest regimen intensification informed by therapeutic drug monitoring. GRADE: Conditional recommendation, very-low-quality evidence. Vote: strongly agree, 53%; agree, 47%.<br><br>Information additionnelle<br><br>Based on the evidence that regimen intensification can improve outcomes, the consensus group suggested this strategy before considering a change in therapy. The statement was a conditional suggestion because of uncertainties of TDM, not uncertainty pertaining to the value of dose intensification. | Recommandations<br><br>Aucune recommandation trouvée. |

| Information extraite | ECCO-ESPGHAN Guideline Update (Van Rheenen 2021) | CAG Clinical Practice Guideline (Mack 2019) | NICE TA187 (2018) |
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| | Patients treated with infliximab should have their first proactive TDM just before the fourth infusion [ie, 14 weeks after the first dose]. Patients at risk for accelerated infliximab clearance during induction [ie, children <30 kg, those with extensive disease, and those with low serum albumin] may have their first proactive TDM at the second or third infusion. The aim is to achieve trough concentrations in the therapeutic range.<br><br>In patients who experience primary non-response to anti-TNF agents, drug trough level [and ADA titre, if available] should be measured at the end of induction [ie, before the fourth infliximab infusion, or before the third adalimumab injection] and in patients with secondary LOR at the time of losing response. Treatment changes should be based on TDM results and the consequent stratification to immunogenic [presence of ADA], pharmacokinetic [low trough concentrations without ADA], and pharmacodynamic loss of response [adequate trough concentrations].<br><br>Patients with low ADA titres may restore response following dose escalation, addition of an immunomodulator, or both, whereas patients with high ADA titre should be switched in-class [from infliximab to adalimumab or vice versa]. Patients with low trough levels without ADA should have a dose increase, and patients with trough levels that are well in range should be switched to an out-of-class biologic. | | |
| Infliximab | Recommandations<br><br>A minimal maintenance threshold of 5 µg/ml for infliximab and 7.5 µg/ml for adalimumab should be targeted for endoscopic healing. Specific phenotypes, in particular perianal fistulising disease, may require even higher drug exposure for fistula healing [≥12.7 µg/ml | Recommandations<br><br>Aucune information relative aux doses des biologiques ou biosimilaires à utiliser. | Recommandations<br><br>For people aged 6–17 years, infliximab is given as a 5-mg/kg intravenous infusion followed by additional 5-mg/kg doses at 2 and 6 weeks after the first dose, then every 8 weeks thereafter. |

| Information extraite | ECCO-ESPGHAN Guideline Update (Van Rheenen 2021) | CAG Clinical Practice Guideline (Mack 2019) | NICE TA187 (2018) |
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| | infliximab]. Infliximab and adalimumab therapy should generally not be abandoned unless drug concentrations are greater than 10 µg/mL.<br><br>Information additionnelle<br><br>At the end of induction [ie, before the fourth infliximab infusion, or before the third adalimumab injection], the target trough level is ≥5 µg/ml for infliximab and ≥ 7.5 µg/ml for adalimumab. In patients at risk for accelerated infliximab clearance during induction, an infliximab concentration ≥25 and ≥15 µg/ml at infusion 2 and 3, respectively, are associated with better outcomes. | | <u>Electronic medicines compendium (EMC 2021)</u><br><br>Paediatric population, Crohn's disease (6 to 17 years)<br><br>5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Available data do not support further infliximab treatment in children and adolescents not responding within the first 10 weeks of treatment.<br><br>Some patients may require a shorter dosing interval to maintain clinical benefit, while for others a longer dosing interval may be sufficient. Patients who have had their dose interval shortened to less than 8 weeks may be at greater risk for adverse reactions. Continued therapy with a shortened interval should be carefully considered in those patients who show no evidence of additional therapeutic benefit after a change in dosing interval.<br><br>The safety and efficacy of Remicade have not been studied in children with Crohn's disease below the age of 6 years. Currently available pharmacokinetic data are described in section 5.2 but no recommendation on a posology can be made in children younger than 6 years. |

**Tableau D-15 Information extraite des guides de pratique clinique pour la polyarthrite rhumatoïde chez l'adulte**

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| Thérapies<br><br>TDM<br><br>Ajustement thérapeutique en lien avec les médicaments biologiques | <u>Recommandations</u><br><br>Pas de référence au TDM<br><br>*Initiation of treatment in DMARD-naive patients with moderate-to-high disease activity*<br><br>Methotrexate monotherapy is strongly recommended over :<br><br>• bDMARD or tsDMARD monotherapy (very low/moderate certainty of evidence).<br>• Combination of methotrexate plus a non–TNF inhibitor bDMARD or tsDMARD (low/very low certainty of evidence)<br><br>Methotrexate monotherapy is conditionally recommended over :<br><br>• Combination of methotrexate plus a TNF inhibitor (low certainty of evidence)<br><br>*Initiation of treatment in csDMARD-treated, but methotrexate-naive, patients with moderate-to-high disease activity*<br><br>Methotrexate monotherapy is conditionally recommended over the combination of methotrexate plus a bDMARD or tsDMARD (moderate/very low certainty of | <u>Recommandations</u><br><br>Pas de référence au TDM<br><br>***NICE NG100 (2018)***<br><br>*Treat-to-target strategy*<br><br>Treat active RA in adults with the aim of achieving a target of remission or low disease activity if remission cannot be achieved (treat-to-target). Achieving the target may involve trying multiple conventional disease-modifying anti-rheumatic drugs (cDMARDs) and biological DMARDs with different mechanisms of action, one after the other. [2018, amended 2020]<br><br>*Initial pharmacological management*<br><br>For adults with newly diagnosed active RA:<br><br>• Offer first-line treatment with cDMARD monotherapy using oral methotrexate, leflunomide or sulfasalazine as soon as possible and ideally within 3 months of onset of persistent symptoms.<br><br>• Consider hydroxychloroquine for first-line treatment as an | <u>Recommandations</u><br><br>Pas de référence au TDM<br><br>Monitoring should be frequent in active disease (every 1–3 months); if there is no improvement by at most 3 months after the start of treatment or the target has not been reached by 6 months, therapy should be adjusted (level of evidence 2b, strength of recommendation B, level of agreement 9.3).<br><br>MTX should be part of the first treatment strategy (level of evidence 1a, strength of recommendation A, level of agreement 9.4).<br><br>If the treatment target is not achieved with the first csDMARD strategy, in the absence of poor prognostic factors, other csDMARDs should be considered (level of evidence 5, strength of recommendation D, level of agreement 8.4).<br><br>If the treatment target is not achieved with the first csDMARD strategy, when and poor prognostic factors are present, a bDMARD or a tsDMARD should be added (level of evidence 1a, strength of recommendation A, level of agreement 9.3). | <u>Recommandations</u><br><br>Pas de référence au TDM<br><br>The cost of RA and of its consequences and treatments, for both the individual and society, should be considered when making treatment decisions (level of evidence NA, grade NA, level of agreement 9.3).<br><br>Follow-up should be provided by a rheumatologist at closely spaced intervals (every 1 to 3 months) as long as the disease is active. Treatment adjustments are in order in patients who fail to improve within 3 months or to achieve their treatment target within 6 months (level of evidence IIb, grade B, level of agreement 9.8).<br><br>In patients with an inadequate response or intolerance to methotrexate, the treatment must be optimized (level of agreement 9.2):<br><br>• In patients with adverse prognostic factors, add-on bDMARD or tsDMARD therapy can be considered, using a TNFa antagonist, abatacept, an IL-6 pathway antagonist, a JAK inhibitor, or, under specific circumstances, rituximab |

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| | evidence; the direction of the beneficial effect is in favor of the nonpreferred option. The certainty of evidence is high for the combination of methotrexate plus a TNF inhibitor and moderate for other bDMARDs).<br><br>*Recommendations for treatment modification in patients treated with DMARDs who are not at target*<br><br>A treat-to-target approach is strongly recommended over usual care for patients who have not been previously treated with bDMARDs or tsDMARDs (low certainty of evidence).<br><br>A treat-to-Target approach is conditionally recommended over usual care for patients who have had an inadequate response to bDMARDs or tsDMARDs (very low certainty of evidence).<br><br>Switching to a bDMARD or tsDMARD of a different class is conditionally recommended over switching to a bDMARD or tsDMARD belonging to the same class for patients taking a bDMARD or tsDMARD who are not at target (very low certainty of evidence). | alternative to oral methotrexate, leflunomide or sulfasalazine for mild or palindromic disease.<br><br>• Escalate dose as tolerated. [2018]<br><br>Consider short-term bridging treatment with glucocorticoids (oral, intramuscular or intra-articular) when starting a new cDMARD. [2018]<br><br>Offer additional cDMARDs (oral methotrexate, leflunomide, sulfasalazine or hydroxychloroquine) in combination in a step-up strategy when the treatment target (remission or low disease activity) has not been achieved despite dose escalation. [2018]<br><br>*Further pharmacological management*<br><br>NICE has published technology appraisal guidance on biological and targeted synthetic DMARDs for RA. For full details, see the NICE Pathway on rheumatoid arthritis.<br><br>***NICE TA375 (2019) – severe RA***<br><br>Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended | bDMARDs and tsDMARDs should be combined with a csDMARD; in patients who cannot use csDMARDs as comedication, IL-6 pathway inhibitors and tsDMARDs may have some advantages compared with other bDMARDs (level of evidence 1a, strength of recommendation A, level of agreement 8.9).<br><br>If a bDMARD* or tsDMARD has failed, treatment with another bDMARD or a tsDMARD should be considered; if one TNF inhibitor therapy has failed, patients may receive an agent with another mode of action or a second TNF inhibitor (*level of evidence 1b, strength of recommendation A, level of agreement 8.9).<br><br>If a patient is in persistent remission after having tapered glucocorticoids, one can consider tapering bDMARDs or tsDMARDs, especially if this treatment is combined with a csDMARD (level of evidence 1b, strength of recommendation A, level of agreement 9.2). | (level of evidence Ib, grade A).<br>• In patients without adverse prognostic factors, a switch to another csDMARD (leflunomide, sulfasalazine) or the combination of several csDMARDs can be considered; if this strategy fails or is contraindicated, targeted therapy (with a bDMARD or tsDMARD) should be considered (level of evidence V, grade D).<br><br>All targeted therapies (bDMARDs* or tsDMARDs) are best used in combination with methotrexate (*level of evidence I1, grade A, level of agreement 9.5).<br><br>Patients who fail a first targeted therapy (bDMARD* or tsDMARD) should be switched to another targeted therapy. In the event of primary failure, a switch to a targeted therapy that has a different mechanism of action may deserve preference (*level of evidence Ia, grade A, level of agreement 9.6).<br><br>In patients who have a sustained remission without glucocorticoid therapy, a decrease in the targeted therapy dosage must be considered (level of evidence IIb, grade B, level of agreement 9.1). |

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| | | as options for treating rheumatoid arthritis, only if:<br><br>• Disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and<br>• Disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and<br><br>Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met.<br><br>***NICE TA485 (2017) – severe RA***<br><br>Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs), only if the disease is severe (a disease activity score [DAS28] of more than 5.1)<br><br>Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis | | |

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| | | in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if the disease is severe (a DAS28 of more than 5.1) and they cannot have rituximab.<br><br>Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to rituximab and at least 1 biological DMARD, only if the disease is severe (a DAS28 of more than 5.1).<br><br>Sarilumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance.<br><br>***NICE TA715 (2021) – moderate RA***<br><br>Adalimumab, etanercept and infliximab, all with methotrexate, are recommended as options for treating active rheumatoid arthritis in adults, only if:<br><br>• Intensive therapy with 2 or more conventional disease-modifying antirheumatic drugs (DMARDs) has not controlled the disease well enough and | | |

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| | | • Disease is moderate (a disease activity score [DAS28] of 3.2 to 5.1).<br><br>Adalimumab and etanercept can be used as monotherapy when methotrexate is contraindicated or not tolerated.<br><br>***NICE TA195 (2013)***<br><br>Rituximab in combination with methotrexate is recommended as an option for the treatment of adults with severe active rheumatoid arthritis who have had an inadequate response to, or are intolerant of, other disease-modifying anti-rheumatic drugs (DMARDs), including at least one tumour necrosis factor (TNF) inhibitor. Treatment with rituximab should be given no more frequently than every 6 months. | | |
| Abatacept | Initial dosing regimen at baseline, 2 and 4 weeks, then q 4 weeks (500 mg in patients < 60 kg, 750 mg in patients 60 kg to 100 kg and 1000 mg in patients > 100 kg)<br><br>125 mg once weekly without a loading dose | ***NICE TA375 (2019)***<br><br>Abatacept is given by intravenous infusion at a dose of 500 mg for a person weighing less than 60 kg, 750 mg for a person weighing between 60 kg and 100 kg, and 1000 mg for a person weighing more than 100 kg. It is given initially at 0, 2 and 4 weeks, then every 4 weeks thereafter. | Aucune information trouvée. | Aucune information trouvée. |

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| Adalimumab | 40 mg SC every two weeks | ***NICE TA375 (2019)***<br><br>Adalimumab is administered subcutaneously as a 40-mg dose every other week. For adalimumab monotherapy, the dose may be increased up to 40 mg per week for people who have a decrease in response.<br><br>***NICE TA715 (2021) – EMC***<br><br>The recommended dose of Humira for adult patients with rheumatoid arthritis is 40 mg adalimumab administered every other week as a single dose via subcutaneous injection. Methotrexate should be continued during treatment with Humira.<br><br>In monotherapy, some patients who experience a decrease in their response to Humira 40 mg every other week may benefit from an increase in dosage to 40 mg adalimumab every week or 80 mg every other week.<br><br>Available data suggest that the clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be reconsidered in a patient not responding within this time period. | Aucune information trouvée. | Aucune information trouvée. |
| Certolizumab pegol | 400 mg at 0, 2, 4 weeks and maintenance 200 mg q other week | ***NICE TA375 (2019)***<br><br>Certolizumab pegol is | Aucune information trouvée. | Aucune information trouvée. |

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| | 400 mg at 0, 2, 4 weeks and maintenance 400 mg q 4 weeks | administered subcutaneously as initial 400-mg doses at 0, 2 and 4 weeks, followed by maintenance doses of 200 mg every 2 weeks. Alternatively, administration of 400 mg every 4 weeks can be considered, once clinical response is confirmed. | | |
| Étanercept | 50 mg once weekly<br><br>25 mg twice weekly | ***NICE TA375 (2019)***<br><br>Etanercept is administered subcutaneously as a 25-mg dose twice weekly or alternatively as a 50-mg dose every week.<br><br>***NICE TA715 (2021) – EMC***<br><br>25 mg Enbrel administered twice weekly is the recommended dose. Alternatively, 50 mg administered once weekly has been shown to be safe and effective. | Aucune information trouvée. | Aucune information trouvée. |
| Golimumab | SC : 50 mg q 4 week<br><br>IV : 2 mg/kg at 0, 4, and q 8 weeks | ***NICE TA375 (2019)***<br><br>Golimumab is administered subcutaneously as a 50-mg dose every month on the same day each month. For people weighing more than 100 kg, a dose of 100 mg may be considered if the disease has an inadequate clinical response after 3–4 doses. | Aucune information trouvée. | Aucune information trouvée. |
| Infliximab | 3mg/kg at 0,2,6 and q 8 weeks<br><br>10 mg/kg at 0, 2, 6, and q 8 weeks | ***NICE TA375 (2019)***<br><br>Infliximab is administered as an intravenous infusion at a dose of | Aucune information trouvée. | Aucune information trouvée. |

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| | | 3 mg/kg, with initial doses at 0, 2 and 6 weeks, and then every 8 weeks thereafter. For disease that has an inadequate response or loss of response after 12 weeks of treatment, consideration may be given to increasing the dose step-wise by approximately 1.5 mg/kg up to a maximum of 7.5 mg/kg every 8 weeks. Alternatively, administration of 3 mg/kg as often as every 4 weeks may be considered.<br><br>***NICE TA715 (2021) – EMC***<br><br>3 mg/kg given based on the body weight (bw) as an intravenous infusion followed by additional 3 mg/kg bw infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Flixabi must be given concomitantly with methotrexate.<br><br>Available data suggest that the clinical response is usually achieved within 12 weeks of treatment. If a patient has an inadequate response or loses response after this period, consideration may be given to increase the dose step-wise by approximately 1.5 mg/kg bw, up to a maximum of 7.5 mg/kg bw every 8 weeks. Alternatively, administration of 3 mg/kg bw as often as every 4 weeks may be considered. If adequate response is achieved, patients should be continued on the selected dose or dose frequency. Continued | | |

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| | | therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment or after dose adjustment. | | |
| Rituximab | Two 1000 mg IV doses 2 weeks apart | ***NICE TA195 (2013)***<br><br>A course of rituximab consists of two 1000-mg intravenous infusions given 2 weeks apart. The SPC specifies that courses of rituximab should be given at intervals of no less than 16 weeks.<br><br>***ECM***<br><br>A course of MabThera consists of two 1000 mg intravenous infusions. The recommended dosage of MabThera is 1000 mg by intravenous infusion followed by a second 1000 mg intravenous infusion two weeks later. The need for further courses should be evaluated 24 weeks following the previous course. Retreatment should be given at that time if residual disease activity remains, otherwise retreatment should be delayed until disease activity returns. Available data suggest that clinical response is usually achieved within 16 - 24 weeks of an initial treatment course. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within this time period. | Aucune information trouvée. | Aucune information trouvée. |

| Information extraite | ACR (Fraenkel 2021) | NICE | EULAR (Smolen 2020) | SFR (Daien 2019) |
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| Sarilumab | 200 mg once every 2 weeks | ***NICE TA485 (2017)***<br><br>The recommended dose of sarilumab is 200 mg administered once every 2 weeks. A reduction in dose from 200 mg once every 2 weeks to 150 mg once every 2 weeks is recommended for management of neutropenia, thrombocytopenia and liver enzyme elevations. Sarilumab is administered subcutaneously using a pre-filled pen or syringe. | Aucune information trouvée. | Aucune information trouvée. |
| Tocilizumab | 4 mg/kg once every 4 weeks<br><br>162 mg once every week | ***NICE TA375 (2019)***<br><br>Tocilizumab is administered as a dose of 8 mg/kg every 4 weeks. | Aucune information trouvée. | Aucune information trouvée. |

**Tableau D-16 Information extraite des guides de pratique clinique pour la spondylarthrite ankylosante chez l'adulte – partie I**

| Information extraite | Korean College of Rheumatology (Park 2020) | American College of Rheumatology (Ward 2019) | APLAR (Tam 2019) | ASAS-EULAR (Van der Heijde 2017) |
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| Indications d'usage<br><br>Ajustement thérapeutique<br><br>Mesure des concentrations sériques ou des anticorps | <u>Recommandations</u><br><br>In AS, bDMARDs should be considered in patients with persistently high disease activity despite conventional treatments including NSAIDs; current practice is to start with TNF inhibitor therapy (LOE: high for TNF inhibitor/moderate for IL-17 inhibitor; SOR: strongly recommended). High agreement (100%).<br><br>**In AS, if the treatment with the first TNF inhibitor has failed, switching to another TNF inhibitors or IL-17 inhibitor should be considered (LOE: low for TNF inhibitor/moderate for IL-17 inhibitor; SOR: weakly recommended for TNF inhibitors, strongly recommended for IL-17 inhibitor). High agreement (100%).** | <u>Recommandations</u><br><br>In adults with active AS despite treatment with NSAIDs, we conditionally recommend treatment with sulfasalazine, methotrexate, or tofacitinib over no treatment with these medications. Sulfasalazine or methotrexate should be considered only in patients with prominent peripheral arthritis or when TNFi are not available (level of evidence : very low to moderate)<br><br>In adults with active AS despite treatment with NSAIDs, we strongly recommend treatment with TNFi over no treatment with TNFi (level of evidence : high).<br><br>We do not recommend any particular TNFi as the preferred choice (level of evidence : moderate)<br><br>In adults with active AS despite treatment with NSAIDs, we strongly recommend treatment with secukinumab or ixekizumab over no treatment with secukinumab or ixekizumab (level of evidence : high).<br><br>In adults with active AS despite treatment with NSAIDs, we conditionally recommend | <u>Recommandations</u><br><br>We strongly recommend the use of biological DMARDs (bDMARDs) in patients with active disease who have failed treatment with 2 different NSAIDs (Vote 86% agreement; grade of evidence moderate).<br><br>Supporting statements :<br><br>• The definition of active disease is considered to be BASDAI ≥4 or Ankylosing Spondylitis Disease Activity Score (ASDAS)-CRP ≥2.1, especially in those with elevated CRP or active inflammation on MRI (Not graded).<br><br>• The evidence shows that bDMARD therapy is effective in achieving good disease control in the long term, with a reduction in complications, for patients with axial SpA (Not graded).<br><br>We strongly recommend using a TNF inhibitor as the initial bDMARD treatment (Vote 100% agreement; grade of evidence very low).<br><br>Supporting statements : | <u>Recommandations</u><br><br>bDMARDs should be considered in patients with persistently high disease activity despite conventional treatments; current practice is to start with TNFi therapy (level of evidence 1a (TNFi) and 1b (IL-17i), grade of recommendation A, level of agreement 93%).<br><br>**If TNFi therapy fails, switching to another TNFi or an anti-IL17 therapy should be considered (level of evidence 2 (TNFi), and 1b (IL-17i), grade of recommendation B (TNFi) and A (IL-17i), level of agreement 97%).**<br><br>If a patient is in sustained remission, tapering of a bDMARD can be considered (level of evidence 2, grade of recommendation B, level of agreement 97%). |

| Information extraite | Korean College of Rheumatology (Park 2020) | American College of Rheumatology (Ward 2019) | APLAR (Tam 2019) | ASAS-EULAR (Van der Heijde 2017) |
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| | | treatment with TNFi over treatment with secukinumab or ixekizumab (level of evidence : very low)<br><br>In adults with active AS despite treatment with NSAIDs and who have contraindications to TNFi, we conditionally recommend treatment with secukinumab or ixekizumab over treatment with sulfasalazine, methotrexate, or tofacitinib (level of evidence : low).<br><br>**In adults with active AS despite treatment with the first TNFi used, we conditionally recommend treatment with secukinumab or ixekizumab over treatment with a different TNFi in patients with primary nonresponse to TNFi (level of evidence : very low).**<br><br>**In adults with active AS despite treatment with the first TNFi used, we conditionally recommend treatment with a different TNFi over treatment with a non-TNFi biologic in patients with secondary nonresponse to TNFi (level of evidence : very low).**<br><br>In adults receiving treatment with TNFi and NSAIDs, we conditionally recommend continuing treatment with TNFi alone compared to continuing both treatments (level of evidence : very low). | • The choice of TNF inhibitor may be influenced by availability, cost, mode of delivery and patient preference (Not graded).<br><br>• Secukinumab is a suitable alternative if TNF inhibitors are contraindicated or unavailable, except in the setting of concomitant inflammatory bowel disease (Not graded).<br><br>**In adults with persistent active axial SpA despite an adequate trial of the first TNFi for at least 12 weeks, we conditionally recommend treatment with another TNFi or secukinumab (Vote 100% agreement; grade of evidence very low).**<br><br>We conditionally recommend continuing bDMARD therapy in patients who respond well to treatment, but a reduced dose or increased interval may be considered in patients in sustained remission (Vote 100% agreement; grade of evidence low). | |

| Information extraite | Korean College of Rheumatology (Park 2020) | American College of Rheumatology (Ward 2019) | APLAR (Tam 2019) | ASAS-EULAR (Van der Heijde 2017) |
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| | | In adults receiving treatment with TNFi and a conventional synthetic antirheumatic drug, we conditionally recommend continuing treatment with TNFi alone over continuing both treatments (level of evidence : very low).<br><br>In adults receiving treatment with a biologic, we conditionally recommend against discontinuation of the biologic (level of evidence : very low to low).<br><br>In adults receiving treatment with a biologic, we conditionally recommend against tapering of the biologic dose as a standard approach (level of evidence : very low to low). | | |
| Adalimumab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. |
| Étanercept | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. |
| Infliximab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. |
| Certolizumab pegol | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. |
| Golimumab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. |
| Ixékizumab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. |

AS: ankylosing spondylitis; bDMARD: biologic disease modifying antirheumatic drug; IL-17: interleukin-17; LOE: level of evidence; NSAID: nonsteroidal anti-inflammatory drug; SOR: strength of recommendation; TNF: tumor necrosis factor; TNFi: TNF inhibitor.

## Tableau D-17 Information extraite des guides de pratique clinique pour spondylarthrite ankylosante chez l'adulte – partie II

| Information extraite | NICE (2016-2021) | Société française de rhumatologie (Wendling 2018) | British Society for Rheumatology (Hamilton 2017) |
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| Indications d'usage<br><br>Ajustement thérapeutique<br><br>Mesure des concentrations sériques ou des anticorps | <u>Recommandations</u><br><br>***NG65 (2017), TA383 (2016), TA497 (2018) et TA407 (2016)***<br><br>Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, NSAIDs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop.<br><br>Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, NSAIDs.<br><br>The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as:<br><br>• a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and | <u>Recommandations</u><br><br>In patients with active axial SpA despite NSAID therapy, the use of biologics (antagonists to TNFa or IL-17) should be considered. TNFa antagonists are usually chosen. In nonradiographic axial SpA with no evidence of inflammation by laboratory tests or MRI, biologics are not indicated, except in highly selected patients (grade A, level of agreement 9.41).<br><br>In patients with active peripheral articular and/or entheseal SpA despite conventional treatment, the administration of a biologic (antagonist of TNFa, IL23, or IL17), usually a TNFa antagonist, should be considered. (In highly selected patients, the use of a phosphodiesterase-4 inhibitor may be considered) (grade A, level of agreement 8.91).<br><br>**When the first biologic fails due to lack of effectiveness or poor tolerance, after an analysis of the reasons of the failure, treatment with a second biologic can be considered (grade A, level of agreement 9.6).**<br><br>In patients with a disease remission or low level of activity sustained for at least 6 months during biologic therapy, a gradual increase in the dosing interval or decrease in the drug dosage can be considered (grade B, level of agreement 9.75). | <u>Recommandations</u><br><br>Patients should be considered for anti-TNF therapy if they have active axSpA (LOE 1+; strength of recommendation B; consensus score 9.6).<br><br>Currently there is insufficient evidence to recommend the use of other biologic agents in axSpA (LOE 1+; strength of recommendation B; consensus score 9.3).<br><br>**In the absence of an initial clinical response by 6 months, or failure to maintain response at two consecutive assessments, withdrawal of that anti-TNF agent should be considered (LOE 4; strength of recommendation D; consensus score 9.4).**<br><br>**In the event of anti-TNF failure due to inefficacy or adverse events, an alternative anti-TNF agent should be offered if clinically appropriate (LOE 2+; strength of recommendation C; consensus score 9.7).**<br><br>There is no evidence to support the withdrawal of anti-TNF therapy in treatment responders (LOE 2+; strength of recommendation B; consensus score 9). |

| Information extraite | NICE (2016-2021) | Société française de rhumatologie (Wendling 2018) | British Society for Rheumatology (Hamilton 2017) |
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| | • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.<br><br>**Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response.**<br><br>**Secukinumab is recommended, within its marketing authorisation, as an option for treating active ankylosing spondylitis in adults whose disease has responded inadequately to conventional therapy (NSAIDs or TNF-alpha inhibitors).**<br><br>***NICE TA718 (2021)***<br><br>**Ixekizumab is recommended as an option for treating active ankylosing spondylitis that is not controlled well enough with conventional therapy, or active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs), in adults. It is recommended only if tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough.**<br><br>Assess response to ixekizumab after 16 to 20 weeks of treatment. Continue treatment only if there is clear evidence of response. | | |

| Information extraite | NICE (2016-2021) | Société française de rhumatologie (Wendling 2018) | British Society for Rheumatology (Hamilton 2017) |
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| Adalimumab | ***NICE TA383 (2016)***<br><br>Adalimumab is administered by subcutaneous injection. The recommended dose regimen for patients with ankylosing spondylitis, and for patients with non-radiographic axial spondyloarthritis, is 40 mg (given as 1 injection) every other week. The summary of product characteristics recommends that continued adalimumab therapy should be carefully reconsidered in patients whose disease does not respond within 12 weeks after starting treatment. | Aucune information trouvée. | Aucune information trouvée. |
| Étanercept | ***NICE TA383 (2016)***<br><br>Etanercept is administered by subcutaneous injection. The recommended dosage for patients with ankylosing spondylitis, and for patients with non-radiographic axial spondyloarthritis, is 25 mg administered twice weekly or 50 mg administered once weekly. The summary of product characteristics recommends that continued etanercept therapy should be carefully reconsidered in patients whose disease does not respond within 12 weeks of starting treatment. | Aucune information trouvée. | Aucune information trouvée. |
| Infliximab | ***NICE TA383 (2016)***<br><br>Infliximab is administered by intravenous infusion. The recommended dosage for patients with ankylosing spondylitis is a 5 mg/kg infusion at weeks 0, 2 and 6, then every 6–8 weeks. The summary of product characteristics states that if there is no response by 6 weeks (that is, after 2 doses), no additional treatment with infliximab should be given. | Aucune information trouvée. | Aucune information trouvée. |

| Information extraite | NICE (2016-2021) | Société française de rhumatologie (Wendling 2018) | British Society for Rheumatology (Hamilton 2017) |
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| | Biosimilar versions of infliximab (Inflectra, Hospira; Remsima, Celltrion/Napp) have a marketing authorisation in the UK for the same indications. The therapeutic indications, dosage and method of administration for Inflectra and Remsima are identical to those for Remicade. | | |
| Certolizumab pegol | ***NICE TA383 (2016)***<br><br>Certolizumab pegol is administered by subcutaneous injection. The recommended loading dosage for patients with ankylosing spondylitis, and for patients with non-radiographic axial spondyloarthritis, is 400 mg (given as 2 injections of 200 mg each) at weeks 0, 2 and 4. The recommended maintenance dose regimen is 200 mg every other week or 400 mg every 4 weeks. The summary of product characteristics recommends that continued certolizumab pegol therapy should be carefully reconsidered if there is no evidence of therapeutic benefit within 12 weeks of starting treatment. | Aucune information trouvée. | Aucune information trouvée. |
| Golimumab | ***NICE TA383 (2016) et TA497 (2018)***<br><br>Golimumab is administered by subcutaneous injection. The recommended dose regimen for patients with ankylosing spondylitis is 50 mg once a month, on the same date each month. The summary of product characteristics recommends that continued golimumab therapy should be carefully reconsidered if there is no evidence of therapeutic benefit within 12–14 weeks of starting treatment (that is, after 3–4 doses). For patients with a body weight greater than 100 kg whose disease does not respond adequately after 4 doses (50 mg each), the summary of product characteristics states that increasing the | Aucune information trouvée. | Aucune information trouvée. |

| Information extraite | NICE (2016-2021) | Société française de rhumatologie (Wendling 2018) | British Society for Rheumatology (Hamilton 2017) |
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| | dosage of golimumab to 100 mg once a month may be considered. If there is still no evidence of therapeutic benefit after 3–4 additional doses of 100 mg, continued golimumab therapy should be carefully reconsidered. | | |
| Ixékizumab | ***NICE TA718 (2021)***<br>The recommended dose is 160 mg (two 80 mg injections) by subcutaneous injection at week 0, followed by 80 mg every 4 weeks.<br><br>Consideration should be given to discontinuing treatment in patients who have shown no response after 16 to 20 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 20 weeks. | Aucune information trouvée. | Aucune information trouvée. |

**Tableau D-18 Information extraite des guides de pratique clinique pour l'arthrite psoriasique chez l'adulte**

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| Indications d'usage<br><br>Ajustement thérapeutique<br><br>Mesure des concentrations sériques ou des anticorps | <u>Recommendations</u><br><br>*Peripheral arthritis*<br><br>In the event of failure with csDMARDs, the use of bDMARDs should be considered. During the review period, studies were identified that reinforce this recommendation for TNF-I, IL-12/23, I-IL-17. If the response to the drugs in this first group is not adequate, it is recommended to start treatment with tofacitinib or abatacept, and in mild cases with apremilast. (Quality of evidence: High. Strength of Recommendation: Strong.)<br><br>**If a bDMARD fails due to inefficacy or adverse events, it can be exchanged for another bDMARD or JAK-i preferably with a different mechanism of action. (Quality of evidence: High.** | <u>Overarching principles</u><br><br>In managing patients with psoriatic arthritis, consideration should be given to each musculoskeletal manifestation and treatment decisions made accordingly (LoA 9.9).<br><br>When managing patients with psoriatic arthritis, non-musculoskeletal manifestations (skin, eye and gastrointestinal tract) should be taken into account; comorbidities such as metabolic syndrome, cardiovascular disease or depression should also be considered (LoA 9.8).<br><br><u>Recommendations</u><br><br>In patients with peripheral arthritis and an inadequate response to at least one csDMARD, therapy with a bDMARD should be | <u>Recommendations</u><br><br>***In adult patients with active PsA despite treatment with a TNFi biologic monotherapy***<br><br>**Switch to a different TNFi biologic over switching to an IL-17i biologic (LoE low). May consider an IL-17i if the patient had a primary TNFi biologic efficacy failure or a TNFi biologic–associated serious adverse event or severe psoriasis.**<br><br>**Switch to a different TNFi biologic over switching to an IL-12/23i biologic (LoE low). May consider an IL-12/23i if the patient had a primary TNFi biologic efficacy failure or a TNFi biologic–associated serious adverse effect or prefers less frequent drug administration.** | <u>Recommendations</u><br><br>Biological therapy is recommended for peripheral PsA patients refractory to at least one cDMARD (GoR A, LoE 1b, LoA 100%).<br><br>Biological therapy is recommended, in monotherapy and in combination with cDMARDs, for all the peripheral manifestations of PsA. Combining the therapy with MTX can increase the survival of the monoclonal, especially the chimeric, TNFi drugs (GoR C, LoE 2b, LoA 100%).<br><br>**In patients with peripheral PsA, and after failure of a TNFi, a change to another biological therapy is recommended, either another TNFi or a drug with a different mechanism of action, such as i-IL12/23 or i-IL17 or a tDMARD** | <u>Recommendations</u><br><br>*Peripheral arthritis*<br><br>**In the case of biologic agent treatment failure due to either adverse events or inefficacy, a large volume of observational data are now available supporting the conditional recommendation of switching either to an alternative biologic agent within a drug class or to a drug with a different mode of action.**<br><br>*Axial disease*<br><br>**NSAIDs are conditionally recommended, usually as an adjunct to further therapy, for patients with an inadequate response to TNFi. Formal published data on switching agents for axial disease are not** | <u>Recommendations</u><br><br>***NG65 (2017), TA199 (2014), TA220 (2016), TA340 (2017), TA537 (2018), TA445 (2020)***<br><br>Etanercept, infliximab and adalimumab are recommended for the treatment of adults with active and progressive psoriatic arthritis when the following criteria are met.<br><br>• The person has peripheral arthritis with 3 or more tender joints and 3 or more swollen joints, and<br><br>• The psoriatic arthritis has not responded to adequate trials of at least 2 standard DMARDs, administered either individually or in combination.<br><br>**Etanercept, adalimumab or infliximab treatment** |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | **Strength of recommendation: Strong.)**<br><br>*Axial disease*<br><br>In the event of failure with NSAIDs, TNF-I agents are recommended as first-line treatment, and in refractory cases or cases with contraindications to TNF-I, the use of I-IL-17 is recommended. The use of I-IL-17 should be considered in patients with extensive or very active psoriasis, I-IL-17 should be avoided in patients with inflammatory bowel disease. Preferably TNF-I (except etanercept) should be used in patients with a history of uveitis. (Quality of evidence: High. Strength of recommendation: Strong.)<br><br>**In the event of an inadequate response to a bDMARD, switching to a bDMARD with a different mechanism of action is** | commenced; when there is relevant skin involvement, an IL-17 inhibitor or IL-12/23 inhibitor may be preferred (LoE 1b, GoR B, LoA 9.4).<br><br>**In patients with peripheral arthritis and an inadequate response to at least one csDMARD and at least one bDMARD, or when a bDMARD is not appropriate, a JAK inhibitor may be considered (LoE 1b, GoR B, LoA 9.2).**<br><br>In patients with unequivocal enthesitis and insufficient response to NSAIDs or local glucocorticoid injections, therapy with a bDMARD should be considered (LoE 1b, GoR B, LoA 9.3).<br><br>In patients with predominantly axial disease which is active and has insufficient response to NSAIDs, therapy with a bDMARD should be considered, which according to | **Switch to an IL-17i biologic over switching to an IL-12/23i biologic (LoE low). May consider an IL-12/23i if the patient has IBD or if the patient prefers less frequent drug administration.**<br><br>**Switch to an IL-12/23i biologic over abatacept (LoE low). May consider abatacept if the patient prefers IV dosing or in patients with recurrent or serious infections.**<br><br>Switch to an IL-12/23i biologic over tofacitinib (LoE low). May consider tofacitinib if the patient prefers an oral therapy.<br><br>***In adult patients with active PsA despite treatment with an IL-17i biologic monotherapy***<br><br>**Switch to a TNFi biologic over switching to an IL-12/23i (LoE very-** | **(apremilast) (GoR B, LoE 1b, 2b, LoA 100%).**<br><br>Biological therapy or tDMARDS (apremilast) are recommended for patients with PsA and enthesitis refractory to NSAID and local treatment (GoR C, LoE 2b, LoA 100%).<br><br>Biological treatment or tDMARDS (apremilast) are recommended for patients with PsA and dactylitis refractory to NSAIDs and local corticosteroid injections (GoR C, LoE 2b, LoA 100%).<br><br>Biological therapy (TNFi or IL17i) is recommended for patients with predominantly axial forms of PsA refractory to NSAIDs (GoR D, LoE 4, LoA 100%). | **available but observational data support switching as in the other domains, leading to a conditional recommendation in the case of inadequate response to TNFi treatment.**<br><br>*Enthesitis*<br><br>**Formal data on treatment switching are not available.**<br><br>*Dactylitis*<br><br>There are efficacy data for biologic agents (such as TNFi or ustekinumab), but **data on treatment switching are not available.**<br><br>*Skin disease*<br><br>**Switching from one DMARD to another, from a DMARD to a biologic treatment, or from one biologic treatment to another can be done.**<br><br>*Nail disease* | **should be discontinued in people whose psoriatic arthritis has not shown an adequate response using the Psoriatic Arthritis Response Criteria (PsARC) at 12 weeks. An adequate response is defined as an improvement in at least 2 of the 4 PsARC criteria (1 of which has to be joint tenderness or swelling score) with no worsening in any of the 4 criteria. People whose disease has a Psoriasis Area and Severity Index (PASI) 75 response at 12 weeks but whose PsARC response does not justify continuation of treatment should be assessed by a dermatologist to determine whether continuing treatment is appropriate on the basis of skin response.**<br><br>Golimumab is recommended as an option for the treatment of active |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | **recommended, restricting this change to the two previously indicated mechanisms of action (TNF-I, I-IL-17) only. There is insufficient evidence of effectiveness with ustekinumab, apremilast, abatacept or tofacitinib, and therefore they are not recommended for axial disease. (Quality of evidence: High. Strength of Recommendation: Strong.)**<br><br>*Enthesitis*<br><br>In enthesitis resistant to NSAIDs and cDMARDs, the use of anti-TNF, ustekinumab, I-IL-17 is recommended. If there is a contraindication to biological therapy, tofacitinib or, if the condition is very mild, apremilast should be considered. (Quality of evidence: High. Strength of recommendation: Strong). | current practice is a TNF inhibitor; when there is relevant skin involvement, IL-17 inhibitor may be preferred (LoE 1b, GoR B, LoA 9.7).<br><br>**In patients who fail to respond adequately to, or are intolerant of a bDMARD, switching to another bDMARD or tsDMARD should be considered*, including one switch within a class† (LoE 1b*, 4†, GoR C, LoA 9.5).**<br><br>In patients in sustained remission, cautious tapering of DMARDs may be considered (LoE 4, GoR C, LoA 9.5).<br><br><u>Research agenda</u><br><br>*Treatment strategy*<br><br>Therapeutic drug monitoring to optimise cost and to support switching between bDMARDs within the same class or to a different mode of action. | **low) May consider switching to IL-12/23i if the patient has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease, or prefers less frequent drug administration.**<br><br>**Switch to a TNFi biologic over switching to a different IL-17i biologic (LoE very low). May consider switching to a different IL-17i if the patient had had a secondary efficacy failure to current IL-17i, or severe psoriasis, or contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.**<br><br>**Switch to an IL-12/23i biologic over switching to a** | | **High-quality data on alternative biologic treatments, including ustekinumab and IL-17 inhibitors, have also been published (36,37), and these agents could be considered alternative biologic therapies to TNFi.** | and progressive psoriatic arthritis in adults only if it is used as described for other TNF-inhibitor treatments and the manufacturer provides the 100 mg dose of golimumab at the same cost as the 50 mg dose.<br><br>Ustekinumab is recommended as an option, alone or in combination with methotrexate, for treating active psoriatic arthritis in adults only when treatment with TNF-alpha inhibitors is contraindicated but would otherwise be considered or the person has had treatment with 1 or more TNF-alpha inhibitors. Ustekinumab is recommended only if the company provides the 90 mg dose of ustekinumab for people who weigh more than 100 kg at the same cost as the 45 mg dose, as agreed in the patient access scheme. Ustekinumab treatment should be |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | *Dactylitis*<br><br>In dactylitis resistant to NSAIDs and cDMARDs, the use of anti-TNF, ustekinumab, IL-17, is recommended. If there is a contraindication to biological therapy, consider tofacitinib or, if the symptoms are very mild, apremilast. (Quality of evidence: High. Strength of recommendation: Strong).<br><br>*Cutaneous psoriasis*<br><br>Patients with moderate or severe disease in whom DMARDs have failed can be treated with I-TNF, ustekinumab, I-IL-17, and while tofacitinib has not yet been approved for plaque psoriasis, apremilast can be used in patients with mild psoriasis or risk factors for developing infections. Certain patients without prior treatment with csDMARDs can also be treated with | *bDMARDs and tsDMARD*<br><br>Duration of biological therapy, including addressing bDMARD dose reduction or discontinuation.<br><br>*Switches*<br><br>Strategies after failures of bDMARDs other than TNFi.<br><br>Repeat switching within a bDMARD class. | **different IL-17i biologic (LoE very low). May consider switching to a different IL-17i if the patient had had a secondary efficacy failure to current IL-17i or severe psoriasis, or if the patient has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.**<br><br>**Switch to an IL-12/23i biologic over adding MTX to an IL-17i biologic (LoE very low). May consider adding MTX to an IL-17i if the patient had had a partial response to the existing regimen.**<br><br>***In adult patients with active PsA despite treatment with an IL-12/23i biologic monotherapy***<br><br>**Switch to a TNFi** | | | stopped if the person's psoriatic arthritis has not shown an adequate response using the PsARC at 24 weeks.<br><br>Ixekizumab alone, or with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults, only if it is used as described in NICE's TA199 or the person has had a tumour necrosis factor (TNF)-alpha inhibitor, but their disease has not responded within the first 12 weeks or has stopped responding after the first 12 weeks or TNF-alpha inhibitors are contraindicated but would otherwise be considered. Assess the response to ixekizumab after 16 weeks of treatment. Only continue treatment if there is clear evidence of response.<br><br>Certolizumab pegol alone, or in combination with methotrexate, is recommended as an |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | bDMARDs. **It is recommended to switch between csDMARDs, from csDMARDs to bDMARDs or between bDMARDs with different mechanisms of action. (Quality of evidence: High. Strength of recommendation: Strong).**<br><br>*Nail psoriasis*<br><br>Few studies of nail Ps have been conducted in patients with PsA, therefore, treatment is primarily based on data from skin psoriasis or nail Ps studies with subgroups of patients with PsA. The efficacy of TNF-I, I-IL-17, ustekinumab, and tofacitinib on nail disorders has been demonstrated and their use is recommended. (Quality of evidence: High. Strength of recommendation: Strong). | | **biologic over switching to an IL-17i biologic (LoE very low). May consider an IL-17i if the patient has severe psoriasis or contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.**<br><br>**Switch to an IL-17i biologic over adding MTX to an IL-12/23i biologic (LoE very low). May consider adding MTX in patients with only partial response to the current therapy or in those who potentially have not had enough time to adequately respond.** | | | option for treating active psoriatic arthritis in adults only if it is used as described in the NICE TA199 or the person has had a tumour necrosis factor (TNF)-alpha inhibitor but their disease has stopped responding after the first 12 weeks.<br><br>Secukinumab alone, or in combination with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults only if it is used as described in the NICE TA199 or the person has had a TNF-alpha inhibitor but their disease has not responded within the first 12 weeks or has stopped responding after 12 weeks or TNF-alpha inhibitors are contraindicated but would otherwise be considered.<br><br>Assess the response to certolizumab pegol and secukinumab after 12 weeks and 16 weeks of treatment |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | | | | | | respectively. Only continue treatment if there is clear evidence of response. |
| Adalimumab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Dose : 40 mg<br><br>Route : subcutaneous<br><br>Frequency : every 2 weeks. | Aucune information trouvée. | ***TA199, EMC***<br><br>The recommended dose of Humira for patients with psoriatic arthritis is 40 mg adalimumab administered every other week as a single dose via subcutaneous injection. Available data suggest that the clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be reconsidered in a patient not responding within this time period. |
| Étanercept | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Dose : 25 or 50 mg<br><br>Route : subcutaneous<br><br>Frequency : 25 mg twice per week (interval of 72–96 h); 50 mg once a week. | Aucune information trouvée. | ***TA199, EMC***<br><br>The recommended dose is 25 mg Enbrel administered twice weekly, or 50 mg administered once weekly. Available data suggest that a clinical response is usually achieved within 12 weeks of treatment. Continued |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | | | | | | therapy should be carefully reconsidered in a patient not responding within this time period. |
| Infliximab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Dose (according to body weight) :<br>5 mg/kg<br><br>Route : i.v. infusion over 2 h<br><br>Frequency : after the first dose, another at 2 and at 6 weeks. Then 1 every 6–8 weeks. | Aucune information trouvée. | ***TA199, EMC***<br><br>5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. |
| Certolizumab pegol | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Dose : 200 mg or 400 mg<br><br>Route : subcutaneous<br><br>Frequency : initially (400 mg at weeks 0, 2 and 4), maintenance (200 mg every 2 weeks or 400 mg every 4 weeks). | Aucune information trouvée. | ***TA445, EMC***<br><br>The recommended starting dose of Cimzia for adult patients is 400 mg (given as 2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4. After the starting dose, the recommended maintenance dose of Cimzia for adult patients with psoriatic arthritis is 200 mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dosing |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | | | | | | of 400 mg every 4 weeks can be considered.<br><br>Available data suggest that clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment. |
| Golimumab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Dose : 50 mg<br><br>Dose : 100 mg in patients with psoriatic arthritis, with a body weight of more than 100 kg who have not achieved an appropriate clinical response after 3 or 4 doses, the dose of golimumab can be increased to 100 mg administered once a month<br><br>Route : subcutaneous<br><br>Frequency : once a month, the same day every month. | Aucune information trouvée. | ***TA220, EMC***<br><br>The recommended dose is 50 mg given once a month, on the same date each month.<br><br>Available data suggest that clinical response is usually achieved within 12 to 14 weeks of treatment (after 3-4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period.<br><br>In patients with a |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | | | | | | body weight of more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit after receiving 3 to 4 additional doses of 100 mg. |
| Ixékizumab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Aucune indication trouvée. | Aucune information trouvée. | ***TA537, EMC***<br><br>160 mg by subcutaneous injection (2×80 mg injections) at week 0, followed by 80 mg (1 injection) every 4 weeks thereafter.<br><br>For patients with concomitant moderate to severe plaque psoriasis, the recommended dosing |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | | | | | | regimen is 160 mg by subcutaneous injection (2×80 mg injections) at week 0, followed by 80 mg (1 injection) at weeks 2, 4, 6, 8, 10 and 12, then maintenance dosing of 80 mg (1 injection) every 4 weeks.<br><br>Consideration should be given to stopping treatment in patients whose disease has shown no response after 16 to 20 weeks of treatment. Some patients with initial partial response may subsequently improve with continued treatment beyond 20 weeks. |
| Sécukinumab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Dose: 150 mg<br><br>Dose refractory to previous biological therapy: 300 mg<br><br>Route : subcutaneous<br><br>Frequency : initially at week 0, 1, 2 and 3. Then monthly maintenance, starting in week 4. | Aucune information trouvée. | ***TA445, EMC***<br><br>For patients with concomitant moderate to severe plaque psoriasis or who are anti-TNFα inadequate responders (IR), the recommended dose is 300 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | | | | | | maintenance dosing. Each 300 mg dose is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.<br><br>For other patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg.<br><br>Consideration should be given to discontinuing treatment in patients who have shown no response by 16 weeks of treatment. Some patients with an initial partial response may subsequently improve with continued treatment beyond 16 weeks. |
| Ustékinumab | Aucune information trouvée. | Aucune information trouvée. | Aucune information trouvée. | Initial dose of 45 mg administered subcutaneously followed by a second dose of 45 mg 4 weeks later and then every 12 weeks. As | Aucune information trouvée. | ***TA340, EMC***<br><br>The recommended posology is an initial dose of 45 mg administered subcutaneously, |

| Information extraite | MCR (Casasola-Vargas 2021) | EULAR (Gossec 2020) | ACR-NFP (Singh 2019) | Spanish Society of Rheumatology (Torre 2018) | GRAPPA Recommendations (Coates 2016) | NICE (2014 à 2020) |
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| | | | | an alternative a dose of 90 mg can be given to patients who weigh over 100 kg. | | followed by a 45 mg dose 4 weeks later, and then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight > 100 kg.<br><br>Consideration should be given to discontinuing treatment in patients who have shown no response up to 28 weeks of treatment. |

csDMARDs: conventional synthetic disease-modifying anti-rheumatic drugs; GoR: grade of recommendation; IL: interleukin; LoA: level of agreement; LoE: level of evidence; NSAIDs: non-steroidal anti-inflammatory drugs; TNFi: inhibiteurs du tumor necrosis factor.

**Tableau D-19 Information extraite des guides de pratique clinique pour l'arthrite juvénile idiopathique**

| Information extraite | ACR (Ringold 2019) | NICE (2018) |
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| Indications d'usage<br><br>Ajustement thérapeutique<br><br>Mesure des concentrations sériques ou des anticorps | <u>Recommandations</u><br><br>In children and adolescents with JIA and polyarthritis initiating treatment with a biologic (etanercept, adalimumab, golimumab, abatacept, or tocilizumab) combination therapy with a DMARD is conditionally recommended over biologic monotherapy. Level of evidence : very low (etanercept, golimumab); low (abatacept, tocilizumab); moderate (adalimumab).<br><br>Combination therapy with a DMARD is strongly recommended for infliximab. Level of evidence : low.<br><br>In children and adolescents with JIA and active polyarthritis :<br><br>Without risk factors, initial therapy with a DMARD is conditionally recommended over a biologic. Level of evidence : low.<br><br>With risk factors, initial therapy with a DMARD is conditionally recommended over a biologic, recognizing that there are situations where initial therapy that includes a biologic may be preferred. Initial biologic therapy may be considered for patients with risk factors and involvement of high-risk joints (e.g., cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage. Level of evidence : low.<br><br>*Subsequent therapy: Low disease activity (cJADAS-10 ≤2.5 and ≥1 active joint)*<br><br>**For children receiving a DMARD and/or biologic, escalating therapy is conditionally recommended over no escalation of therapy. Escalation of therapy may include: intraarticular glucocorticoid injection(s), optimization of DMARD or biologic dose (if not at optimal dosage), trial of methotrexate if not done, and adding or changing biologic. Level of evidence : very low.**<br><br>*Subsequent therapy: moderate/high disease activity (cJADAS-10 >2.5)* | <u>Recommendations</u><br><br>***TA373 (2018)***<br><br>Abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is:<br><br>• for abatacept, people 6 years and older whose disease has responded inadequately to other disease-modifying anti-rheumatic drugs (DMARDs) including at least 1 tumour necrosis factor (TNF) inhibitor<br><br>• for adalimumab, people 2 years and older whose disease has responded inadequately to 1 or more DMARD<br><br>• for etanercept, people 2 years and older whose disease has responded inadequately to, or who are intolerant of, methotrexate<br><br>• for tocilizumab, people 2 years and older whose disease has responded inadequately to previous therapy with methotrexate.<br><br>Adalimumab and etanercept are recommended, within their marketing authorisations, as options for treating enthesitis-related JIA, that is, for people 6 years and older (adalimumab) and 12 years and older (etanercept) whose disease has responded inadequately to, or who are intolerant of, conventional therapy.<br><br>Etanercept is recommended, within its marketing authorisation, as an option for treating psoriatic JIA, that is, in people aged 12 years and over whose disease has responded inadequately to, or who are intolerant of, methotrexate. |

| Information extraite | ACR (Ringold 2019) | NICE (2018) |
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| | If patient is receiving DMARD monotherapy :<br><br>• Adding a biologic to original DMARD is conditionally recommended over changing to a second DMARD. Level of evidence : low.<br><br>• Adding a biologic is conditionally recommended over changing to triple DMARD therapy. Level of evidence : low.<br><br>**If patient is receiving first TNFi (± DMARD):**<br><br>• **Switching to a non-TNFi biologic (tocilizumab or abatacept) is conditionally recommended over switching to a second TNFi. A second TNFi may be appropriate for patients with good initial response to their first TNFi (i.e., secondary failure). Level of evidence : very low.**<br><br>If patient is receiving second biologic:<br><br>• Using TNFi, abatacept, or tocilizumab (depending on prior biologics received) is conditionally recommended over rituximab. Level of evidence : very low.<br><br>In children and adolescents with active sacroiliitis despite treatment with NSAIDs : adding TNFi is strongly recommended over continued NSAID monotherapy. Level of evidence : low.<br><br>In children and adolescents with active enthesitis despite treatment with NSAIDs : using a TNFi is conditionally recommended over methotrexate or sulfasalazine. Level of evidence : low | |
| Adalimumab | Aucune information trouvée. | *Polyarticular juvenile idiopathic arthritis from 2 years of age*<br><br>The recommended dose of Humira for patients with polyarticular juvenile idiopathic arthritis from 2 years of age is based on body weight.<br><br>10 kg to < 30 kg : 20 mg every other week<br><br>≥ 30 kg : 40 mg every other week |

| Information extraite | ACR (Ringold 2019) | NICE (2018) |
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| | | Available data suggest that clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be carefully reconsidered in a patient not responding within this time period.<br><br>There is no relevant use of Humira in patients aged less than 2 years for this indication.<br><br>*Enthesitis-related arthritis*<br><br>The recommended dose of Humira for patients with enthesitis-related arthritis from 6 years of age is based on body weight.<br><br>15 kg to < 30 kg : 20 mg every other week<br><br>≥ 30 kg : 40 mg every other week<br><br>Humira has not been studied in patients with enthesitis-related arthritis aged less than 6 years. |
| Étanercept | Aucune information trouvée. | ***EMC***<br><br>The recommended dose is 0.4 mg/kg (up to a maximum of 25 mg per dose), given twice weekly as a subcutaneous injection with an interval of 3-4 days between doses or 0.8 mg/kg (up to a maximum of 50 mg per dose) given once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months.<br><br>No formal clinical trials have been conducted in children aged 2 to 3 years. However, limited safety data from a patient registry suggest that the safety profile in children from 2 to 3 years of age is similar to that seen in adults and children aged 4 years and older, when dosed every week with 0.8 mg/kg subcutaneously.<br><br>There is generally no applicable use of Enbrel in children aged below 2 years in the indication juvenile idiopathic arthritis. |
| Infliximab | Aucune information trouvée. | ***EMC***<br><br>*Juvenile idiopathic arthritis, psoriatic arthritis and ankylosing spondylitis* |

| Information extraite | ACR (Ringold 2019) | NICE (2018) |
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| | | The safety and efficacy of Remicade in children and adolescents younger than 18 years for the indications of juvenile idiopathic arthritis, psoriatic arthritis and ankylosing spondylitis have not been established. No recommendation on a posology can be made.<br><br>*Juvenile rheumatoid arthritis*<br><br>The safety and efficacy of Remicade in children and adolescents younger than 18 years for the indication of juvenile rheumatoid arthritis have not been established. No recommendation on a posology can be made. |
| Abatacept | Aucune information trouvée. | ***TA373 (2018)***<br><br>The dose of abatacept depends on body weight. For children and young people who weigh less than 75 kg, the dose is 10 mg/kg. For young people weighing over 75 kg, the adult dosing regimen applies, up to a total dose of 1000 mg per administration. Abatacept is given at 2 and 4 weeks after the initial intravenous infusion and then every 4 weeks. |
| Tocilizumab | Aucune information trouvée. | ***TA373 (2018) - JIA***<br><br>The dose of tocilizumab is 8 mg/kg once every 4 weeks in patients weighing 30 kg or more or 10 mg/kg once every 4 weeks in patients weighing less than 30 kg. The summary of product characteristics suggests stopping tocilizumab if a response to treatment is not seen within 12 weeks.<br><br>***TA238 (2014) – systemic JIA***<br><br>The recommended dose is 8 mg/kg in patients weighing 30 kg or more, and 12 mg/kg in patients weighing less than 30 kg.<br><br>***EMC (sJIA)***<br><br>The recommended posology in patients above 2 years of age is 8 mg/kg once every 2 weeks in patients weighing greater than or equal to 30 kg or 12 mg/kg once every 2 weeks in patients weighing less than 30 kg. The dose should be calculated based on the patient's body weight at each administration. A change in dose should only be based on a |

| Information extraite | ACR (Ringold 2019) | NICE (2018) |
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| | | consistent change in the patient's body weight over time.<br><br>***EMC (pJIA)***<br><br>The recommended posology in patients above 2 years of age is 8 mg/kg once every 4 weeks in patients weighing greater than or equal to 30 kg or 10 mg/kg once every 4 weeks in patients weighing less than 30 kg. The dose should be calculated based on the patient's body weight at each administration. A change in dose should only be based on a consistent change in the patient's body weight over time. |

**Tableau D-20 Information extraite des guides de pratique clinique pour le psoriasis en plaques chez l'adulte**

| Information extraite | Smith *et al.*, 2020 (British Association of Dermatologists) | Menter *et al.*, 2019 (Joint AAD-NPF guidelines) | Amatore *et al.*, 2019 (French Guidelines) | Gisondi *et al.*, 2017 (Italian Guidelines) | Canadian Psoriasis Guidelines (2016) | NICE CG153 TA146, TA103, TA350, TA442, TA180, TA511, TA521, TA596, TA134 |
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| Ajustement thérapeutique<br><br>Conduite en cas d'inefficacité | Recommandations<br><br>When to consider dose escalation/ interval reduction<br><br>R20 (↑: weak recommendation for) Consider escalating the dose of or reducing the interval for biologic therapy in adults and when an inadequate primary response might be due to insufficient drug exposure (e.g. in people who are obese and/or whose psoriasis relapses during the treatment cycle and/or if the drug level is known to be subtherapeutic). Take into account that this may be associated with an increased risk of infection/adverse events and, depending on the drug, off-licence and may not be approved by NICE and therefore not funded. | Recommandations<br><br>General comments and special circumstances<br><br>Time frame to assess response to treatment with TNF-a inhibitors<br><br>Definitive response (positive or negative) to treatment with most TNF-a inhibitors is best ascertained after 12 to 16 weeks of continuous therapy, except for infliximab, for which the best time is after 8 to 10 weeks. Consider dose escalation, an increase in frequency, or the addition of other modalities (such as topical corticosteroids or vitamin D analogues, methotrexate, acitretin, apremilast, or NB-UVB) in partially responding patients. Particularly in infliximab, consider an increase in dosing frequency before an | Recommandations<br><br>Voir les recommandations spécifiques aux agents biologiques. | Recommandations<br><br>Information supplémentaire<br><br>The time point to assess treatment goals is at the end of induction therapy (i.e. weeks 12–16). During maintenance treatment, an assessment of treatment goals should be made in intervals given by the safety monitoring recommendations (usually every 8–12 weeks). In the case that the goal is not met, there are several strategies that may increase efficacy such as increasing the dose, reducing the time interval between administrations or adding another drug (combination therapy). However, this may be an off-label drug use, because such variations are not | Recommandations<br><br>Exacerbation and Flare of Psoriasis<br><br>If new-onset psoriasis does not respond to conventional psoriasis therapy, consider switching to another TNF inhibitor (Refs. 2, 3, LoE 3) or to an IL inhibitor (Ref. 4, LoE 3). Grade D). | Recommandations<br><br>Consider changing to an alternative biological drug in adults if:<br><br>• the psoriasis does not respond adequately to a first biological drug as defined in NICE technology appraisals[8] (at 10 weeks after starting treatment for infliximab, 12 weeks for etanercept, ixekizumab and secukinumab, and 16 weeks for adalimumab and ustekinumab; primary failure) or<br><br>• the psoriasis initially responds adequately but subsequently |

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| | R21 (↑↑) When a person's psoriasis responds inadequately to a second or subsequent biological agent, review treatment goals, seek advice from a dermatologist with expertise in biologic therapy and consider any of the following strategies:<br>• reiterate advice about modifiable factors contributing to poor response such as obesity and poor adherence (intentional or nonintentional)<br>• consider whether drug exposure is adequate (see R20)<br>• optimize adjunctive therapy (e.g. switch from oral to subcutaneous methotrexate) | increase in dose in terms of mg/kg.<br><br>Patient weight and response to treatment with TNF-a inhibitors<br><br>Compared with lower-weight patients, overweight or obese patients are less likely to respond to TNF-a inhibitors. Therefore, overweight and obese patients frequently require a shorter dose interval or higher doses to achieve a satisfactory response. However, this effect is abrogated with infliximab, for which weight-based dosing is used. TNF-a-inhibitors may display better responses with doses higher than the FDA-approved dose. In contrast, on the basis of phase II studies and expert opinion, some patients might tolerate and respond to dosing at lower than the FDA-approved dose.<br><br>Time frame to assess | | backed up by the summary of product characteristics.<br><br>Drug monitoring could be adapted according to the specific patient's characteristics including comorbidities. Most of the recommendations are in line with the recent S3 European guidelines.<br><br>When patients lose an adequate response to biological drugs, the possible options include increasing the dose and/or shortening the dosing interval, combination therapy with a topical or another systemic treatment, or switching to a different drug. | | loses this response, (secondary failure) or<br><br>• the first biological drug cannot be tolerated or becomes contraindicated. |

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| | • switch to an alternative biological agent<br><br>• alternative or supplementary nonbiologic therapy approaches (e.g. inpatient topical therapy, phototherapy or systemic therapies). | response to treatment with IL-12/IL-23 inhibitors<br><br>Definitive response (positive or negative) to treatment with ustekinumab is best ascertained after 12 weeks of continuous therapy. Consider dose escalation (eg, increasing dosing frequency to every 8 weeks or increasing the dose from 45 mg to 90 mg) or the addition of other modalities (such as topical corticosteroids or vitamin D analogues, methotrexate, acitretin, or ultraviolet light) in partially responding patients.<br><br>Patient weight and response to treatment with IL-12/IL-23 inhibitors<br><br>Like other biologic therapies, ustekinumab displays higher responses with higher doses. Overweight or obese | | | | |

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| | | patients often need the higher dose (90 mg) of ustekinumab to achieve the response of lower-weight patients taking the 45 mg dose. Additionally, serum concentrations of ustekinumab were also affected by weight, with lower serum concentrations found in heavier patients at each dose. However, some patients might tolerate and respond to lower dosing (eg, longer intervals of time between doses).<br><br>Time frame to assess response to treatment with IL-17 inhibitors Definitive response (positive or negative) to treatment with IL-17 antagonists is best ascertained after 12 weeks of continuous therapy. Consider dose escalation in partially responding patients. Consider the addition of other modalities (such as topical | | | | |

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| | | corticosteroids, methotrexate, or ultraviolet light) in partially responding patients. Although there are no published data supporting combination therapy for the IL-17 inhibitors, there is no reason to consider such combination unsafe. Given their similar mechanism of action, the efficacies of all IL-17 antagonists are comparable.<br><br>Time frame to assess response to treatment with IL-23 inhibitors<br><br>Definitive response (positive or negative) to treatment with IL-23 antagonists is best ascertained after 12 weeks of continuous therapy. Consider dose escalation in partially responding patients. Consider the addition of other modalities (such as topical corticosteroids or vitamin D analogues, | | | | |

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| | | methotrexate, or ultraviolet B light) in partially responding patients. Although there are no published data supporting combination therapy for the IL-23 inhibitors, there is no reason to consider such combination therapy unsafe. | | | | |
| Adalimumab | Biological agent<br><br>Adalimumab : 40 mg every other week<br><br>Suggested dose-escalation/interval-reduction strategy<br><br>40 mg weekly | Recommendations (Strength)<br><br>The recommended starting dose of adalimumab is 80 mg taken as 2 self-administered subcutaneous 40-mg injections of the initial dose, followed by a 40-mg self-administered subcutaneous injection 1 week later, followed by 40 mg self-administered every 2 weeks thereafter (strength of recommendation A).<br><br>A maintenance dose of adalimumab 40 mg/week is | Dosing scheme<br><br>s.c. administration.<br><br>Loading dose of 80 mg at W0, 40 mg W1, then 40 mg every other week.<br><br>If inadequate response at W16: possibility of transient increase in the dosing frequency to 40 mg every week (Grade B). The dose should subsequently be reduced again if an adequate response is achieved. If an adequate response is not achieved 4 months after increasing the dosing | Dosage<br><br>Loading dose at is 80 mg s.c., followed by 40 mg every other week, beginning 1 week after the induction dose. Patients with inadequate response beyond week 16 may benefit from an increase in dosing frequency to 40 mg every week. | Aucune information trouvée. | **TA146 (2014)**<br><br>Adalimumab should be discontinued in people whose psoriasis has not responded adequately at 16 weeks. An adequate response is defined as either: a 75% reduction in the PASI score (PASI 75) from when treatment started, or a 50% reduction in the PASI score (PASI 50) and a five-point reduction in DLQI from start of treatment.<br><br>The recommended dosage for adalimumab is an |

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| | | recommended for better disease control in some patients (strength of recommendation A).<br><br>(Level of evidence I-II) | frequency, ADA should be stopped (Expert opinion).<br><br>No weight—dose adjustment for obese patients. | | | initial 80 mg dose administered by subcutaneous injection, followed by 40 mg given subcutaneously every other week starting 1 week after the initial dose. |
| Brodalumab | Currently, a dose-escalation/interval-reduction strategy is not applicable to brodalumab, guselkumab, risankizumab or secukinumab. | Recommendations (Strength)<br><br>The recommended dose of brodalumab is 210 mg by self-administered subcutaneous injection at week 0, week 1, and week 2 followed by 210 mg every 2 weeks (strength of recommendation A).<br><br>(Level of evidence I-II) | Aucune information trouvée | Aucune information trouvée | Aucune information trouvée | TA511 (2018)<br><br>Stop brodalumab at 12 weeks if the psoriasis has not responded adequately.<br><br>The recommended dose is 210 mg administered by subcutaneous injection at weeks 0, 1 and 2, followed by 210 mg every 2 weeks. |
| Étanercept | Biological agent<br><br>Etanercept : 50 mg once weekly<br><br>Suggested dose-escalation/interval-reduction strategy<br><br>50 mg twice weekly | Recommendations (Strength)<br><br>The recommended starting dose of etanercept is 50 mg taken as a self-administered subcutaneous injection twice weekly | Dosing scheme<br><br>s.c. administration: 50 mg BIW for up to 12 weeks, followed by 50 mg QW is a more effective strategy than 50 mg QW from the beginning of treatment (Grade A). | Dosage<br><br>2 x 50 mg weekly from week 0 to 12 (induction phase) and then 50 mg weekly thereafter (maintenance phase) by s.c. injection. | Aucune information trouvée | **TA103 (2014)**<br><br>Etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. Further |

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| | | for 12 consecutive weeks (Strength of recommendation A).<br><br>The recommended maintenance dose of etanercept after the initial 12 weeks is 50 mg once weekly. Etanercept administered at a dose of 50 mg twice weekly is more efficacious than a dose of 50 mg once weekly and may be required for better disease control in some patients (Strength of recommendation A).<br><br>(Level of evidence I-III) | Possibility of intermittent therapy (grade C).<br><br>No weight–dose adjustment for obese patients. | | | treatment cycles are not recommended in these patients.<br><br>Etanercept is administered by subcutaneous injection at a dose of 25 mg twice weekly. Alternatively, 50 mg given twice weekly may be used for up to 12 weeks followed, if necessary, by a dose of 25 mg twice weekly. The SPC states that treatment with etanercept should continue until remission is achieved, for up to 24 weeks. Treatment should be discontinued in patients who show no response after 12 weeks. |
| Guselkumab | Currently, a dose-escalation/interval-reduction strategy is not applicable to brodalumab, guselkumab, risankizumab or secukinumab. | Recommendations (Strength)<br><br>The recommended dose of guselkumab is 100 mg by self-administered subcutaneous injection at week 0, week 4, and every 8 weeks thereafter | Aucune information trouvée | Aucune information trouvée | Aucune information trouvée | TA521<br><br>Stop guselkumab treatment at 16 weeks if the psoriasis has not responded adequately.<br><br>The recommended dosage of guselkumab is |

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| | | (strength of recommendation A).<br><br>(Level of evidence I) | | | | 100 mg by subcutaneous injection at weeks 0 and 4, followed by a 100 mg maintenance dose every 8 weeks. Consideration should be given to stopping treatment in people whose disease has shown no response after 16 weeks of treatment. |
| Infliximab | Biological agent<br><br>Infliximab : 5 mg/kg every 8 weeks<br><br>Suggested dose-escalation/interval-reduction strategy<br><br>5 mg/kg every 6 weeks | Recommendations (Strength)<br><br>The recommended starting dose of infliximab is an infusion of 5 mg/kg administered at week 0, 2, and 6, and thereafter it is administered every 8 weeks (strength of recommendation A).<br><br>Infliximab is recommended to be administered at a more frequent interval (less than every 8 weeks and as frequently as every 4 weeks during the maintenance phase) and/or at a higher | Dosing scheme<br><br>Intravenous administration (day care hospital unit): 5 mg/kg given at W0, W2, W6, every 8 weeks thereafter (continuous treatment is recommended, Grade A).<br><br>Possibility of increasing dosage or reducing administration intervals (Grade C). If loss of efficacy to standard dose maintenance therapy occurs: 5 mg/kg every 6 weeks (Expert opinion). | Dosage<br><br>5 mg/kg bodyweight at weeks 0, 2 and 6 (induction phase) and then every 8 weeks thereafter (maintenance phase). | Aucune information trouvée | TA134 (2010)<br><br>Infliximab treatment should be continued beyond 10 weeks only in people whose psoriasis has shown an adequate response to treatment within 10 weeks.<br><br>Infliximab is given as a 5-mg/kg intravenous infusion over a 2-hour period followed by additional 5-mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. |

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| | | dose up to 10 mg/kg for better disease control in some adult patients (strength of recommendation B).<br><br>(Level of evidence I-III) | | | | |
| Ixékizumab | Biological agent<br><br>Ixekizumab : 80 mg every 4 weeks<br><br>Suggested dose-escalation/interval-reduction strategy<br><br>80 mg every 2 weeks | Recommendations (strength)<br><br>The recommended starting dose of ixekizumab is 160 mg by self-administered subcutaneous injection followed by 80 mg at week 2, 4, 6, 8, 10, and week 12 (strength of recommendation A)<br><br>The recommended maintenance dose of ixekizumab after the initial 12 weeks is 80 mg every 4 weeks (strength of recommendation A).<br><br>(Level of evidence I-II) | Dosing scheme<br><br>s.c. administration.<br><br>Loading dose of 160 mg, 80 mg every other week until week 12, then 80 mg every 4 weeks.<br><br>No weight–dose adjustment | Aucune information trouvée | Aucune information trouvée | TA442 (2017)<br><br>Stop ixekizumab treatment at 12 weeks if the psoriasis has not responded adequately.<br><br>Recommended dose and schedule : by subcutaneous injection; 160 mg at week 0, followed by 80 mg every 2 weeks until week 12. After week 12, 80 mg every 4 weeks. |
| Risankizumab | Suggested dose-escalation/interval-reduction strategy<br><br>Currently, a dose- | Recommendations (strength)<br><br>The approved dose will likely be 150 mg | Aucune information trouvée | Aucune information trouvée | Aucune information trouvée | TA596 (2019)<br><br>Stop risankizumab treatment at 16 weeks if the psoriasis has |

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| | escalation/interval-reduction strategy is not applicable to brodalumab, guselkumab, risankizumab or secukinumab. | given by self-administered subcutaneous injection at week 0, week 4, and then every 12 weeks (strength of recommendation A).<br><br>(Level of evidence I) | | | | not responded adequately.<br><br>Risankizumab is administered by subcutaneous injection at a dose of 150 mg at weeks 0 and 4, and then every 12 weeks. Consideration should be given to stopping treatment in people whose condition has shown no response after 16 weeks of treatment. |
| Sécukinumab | Suggested dose-escalation/interval-reduction strategy<br><br>Currently, a dose-escalation/interval-reduction strategy is not applicable to brodalumab, guselkumab, risankizumab or secukinumab. | Recommendations (strength)<br><br>The recommended starting dose of secukinumab is 300 mg by self-administered subcutaneous injection at week 0, 1, 2, 3, and 4, followed by 300 mg every 4 weeks (strength of recommendation A).<br><br>The recommended maintenance dose of secukinumab after the initial 12 weeks is 300 mg every 4 weeks (strength of recommendation A) | Dosing scheme<br><br>s.c. administration: 300 mg, delivered in two injections of 150 mg each.<br><br>300 mg at W0, 1, 2, 3, 4 and then 300 mg every 4 weeks.<br><br>No weight–dose adjustment. | Dosage<br><br>300 mg (given as two s.c. injections of 150 mg) with initial dosing at weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at week 4 | Aucune information trouvée | TA350 (2015)<br><br>Secukinumab treatment should be stopped in people whose psoriasis has not responded adequately at 12 weeks. Further treatment cycles are not recommended in these people.<br><br>Secukinumab is given subcutaneously. The recommended dosage is 300 mg at weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at week 4. |

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| | | Secukinumab is recommended at a dose of 300 mg, which is more effective than 150 mg (strength of recommendation A)<br><br>(Evidence level I-II) | | | | |
| Ustékinumab | Biological agent<br><br>Ustekinumab : 45 mg every 12 weeks (≤ 100 kg) or 90 mg every 12 weeks (> 100 kg)<br><br>Suggested dose-escalation/interval-reduction strategy<br><br>90 mg every 8 or 12 weeks (≤ 100 kg) or 90 mg every 8 weeks (> 100 kg) | Recommendations (strength)<br><br>The recommended starting doses of ustekinumab are as follows: (a) For patients weighing ≤ 100 kg, 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks (b) For patients weighing > 100 kg, 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks (strength of recommendation A).<br><br>The recommended alternate dosage for | Dosing scheme<br><br>s.c. administration: 45 mg at Week 0, Week 4 and then every 12 weeks.<br><br>Adjusted for patients >100 kg: same scheme, but with a 90 mg dose.<br><br>Suggested dose-escalation strategy (off-license)<br><br>90 mg every 12 weeks (<100 kg) or 90 mg every 8 weeks (>100 kg) (Grade C). | Dosage<br><br>45 mg for patients with a bodyweight of ≤100 kg and 90 mg for those >100 kg at weeks 0 and 4 (induction), then every 12 weeks. | Aucune information trouvée | TA180 (2009)<br><br>Ustekinumab treatment should be stopped in people whose psoriasis has not responded adequately by 16 weeks after starting treatment.<br><br>The recommended dose of ustekinumab is 45 mg for people who weigh 100 kg or less, and 90 mg for people who weigh over 100 kg. An initial dose of ustekinumab is administered subcutaneously at week 0, followed by another dose at week 4, and then a further dose every 12 weeks.<br><br>The SPC recommends that people whose body |

| Information extraite | Smith *et al.*, 2020 (British Association of Dermatologists) | Menter *et al.*, 2019 (Joint AAD-NPF guidelines) | Amatore *et al.*, 2019 (French Guidelines) | Gisondi *et al.*, 2017 (Italian Guidelines) | Canadian Psoriasis Guidelines (2016) | NICE CG153 TA146, TA103, TA350, TA442, TA180, TA511, TA521, TA596, TA134 |
|---|---|---|---|---|---|---|
| | | ustekinumab is administered at higher doses (90 mg instead of 45 mg in patients weighing ≤ 100 kg) or at a greater frequency of injection (eg, every 8 weeks in its maintenance phase) for those with an inadequate response to standard dosing (strength of recommendation A).<br><br>(Level of evidence I-III). | | | | weight exceeds 100 kg should receive a dose of 90 mg of ustekinumab. This would be double the cost of the 45 mg dose indicated for the treatment of a person who weighs 100 kg or less. However, the manufacturer has proposed a patient access scheme to the Department of Health. Under the scheme, for people who weigh more than 100 kg and who are prescribed the 90 mg dose (two 45 mg vials), the Ustekinumab for the treatment of adults with moderate to severe psoriasis, the manufacturer will provide both vials at the cost of a single vial. |

ADA: adalimumab; BIW : biweekly; DLQI: _____; ETA: étanercept; IFX: infliximab; kg : kilogramme; mg: milligramme; PASI: _____; PGA: _____; SQ : subcutaneous; UST: ustékinumab.

**Tableau D-21 Information extraite des guides de pratique clinique pour la dermatite atopique**

| Information extraite | Werfel 2021 (S2k-guideline update) | Agache 2021 (EAACI Biological Guidelines) | Lansang 2019 (Canadian Dermatology Association) | NICE 2018 (TA534) |
|---|---|---|---|---|
| Indications d'usage<br><br>Conduite en cas d'inefficacité<br><br>Ajustement thérapeutique<br><br>Mesure des concentrations sériques ou des anticorps | *Recommandations d'usage*<br><br>Dupilumab can be recommended for the treatment of chronic, moderate to severe AD in adolescents aged 12 years and older and in adults who cannot be adequately treated with topical medications alone (Strong consensus).<br><br>Dupilumab may also be considered for treating children below 12 years of age with treatment-refractory, severe AD. This is an off-label treatment option. Expert recommendations on dosage in children (≥ 6 months of age) are available (Consensus).<br><br>In cases of evident eczema, a combination of dupilumab with topical anti-inflammatory medication is recommended (Strong consensus). | *Recommandations d'usage*<br><br>Dupilumab is recommended in adults and in the paediatric population 12–17 years old with atopic dermatitis* to:<br><br>• Reduce disease activity as reflected by SCORAD, EASI, IGA (Strong recommendation).<br><br>• Reduce rescue** and background*** medication (Strong recommendation).<br><br>• Improve quality of life (Strong recommendation).<br><br>Dupilumab has demonstrated a good safety profile however drug-related AEs should be periodically monitored (Conditional recommendation).<br><br>*population: moderate-to-severe AD not adequately controlled with topical prescription therapies or when those therapies are not advisable.<br><br>**Rescue refers to « on demand ».<br><br>**Background medication includes systemic and topical treatment.<br><br>Dupilumab is recommended in the paediatric population 6–11 years old with atopic dermatitis* to:<br><br>• Reduce disease activity as | *Recommandations d'usage*<br><br>Systemic therapy is warranted for pediatric patients with AD who have inadequate disease control based on clinical signs, symptoms, or QoL impact, despite appropriate topical therapy and/or phototherapy (Voting Result: 4,7,1,0,0).<br><br>Systemic therapies should be chosen based on the available evidence for their use in the pediatric AD population. Patient-, disease-, and treatment-related factors must be taken into account. Dupilumab is currently the only systemic therapy approved for long-term use in moderate-to-severe AD for patients 12-17 years of age (Voting Result: 5,7,0,0,0).<br><br>*Voting results reflect number of authors voting Strongly Agree, Agree, Neither Agree nor Disagree, Disagree, or Strongly Disagree, respectively. | *Recommandations d'usage*<br><br>Dupilumab is recommended as an option for treating moderate to severe atopic dermatitis in adults, only if:<br><br>• the disease has not responded to at least 1 other systemic therapy, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are contraindicated or not tolerated<br><br>• the company provides dupilumab according to the commercial arrangement.<br><br>Stop dupilumab at 16 weeks if the atopic dermatitis has not responded adequately. An adequate response is:<br><br>• at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started and<br><br>• at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started. |

| Information extraite | Werfel 2021 (S2k-guideline update) | Agache 2021 (EAACI Biological Guidelines) | Lansang 2019 (Canadian Dermatology Association) | NICE 2018 (TA534) |
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| | | reflected by EASI and IGA (Conditional recommendation as per expert opinion).<br>• Improve quality of life (Conditional recommendation as per expert opinion).<br><br>Dupilumab has demonstrated a good safety profile however drug-related AEs should be periodically monitored (Conditional recommendation as per expert opinion).<br><br>*Recommandations en lien avec l'efficacité*<br><br>The evaluation of response should be done after 16 weeks of treatment (Conditional recommendation, expert opinion based).<br><br>As there are no validated criteria for defining response to dupilumab in AD the GDG recommends a composite end point combing clinical parameters (disease severity and QoL) with biomarkers related to disease activity and severity (Conditional recommendation, expert opinion based).<br><br>For the clinical end points, a pre-established cut-off reached through shared decision-making with the patient should be used (Conditional recommendation, expert opinion based).<br><br>Stopping dupilumab should be considered if a significant AE | | |

| Information extraite | Werfel 2021 (S2k-guideline update) | Agache 2021 (EAACI Biological Guidelines) | Lansang 2019 (Canadian Dermatology Association) | NICE 2018 (TA534) |
|---|---|---|---|---|
| | | occurs (Conditional recommendation, expert opinion based).<br><br>*Lacunes à combler*<br><br>Standardising the use in clinical practice<br><br>1. Criteria for responders and suboptimal response(early stopping rules)<br><br>2. When to assess response<br><br>3. The difference between fast and slow responders<br><br>4. Switching rules<br><br>5. Duration of treatment in responders (late stopping rules)<br><br>6. Long-term treatment regimen in responders: longer interval, down-dosing, possibility of stopping treatment, switch to strategies like topical application, etc.<br><br>7. How to switch from other systemic treatment, such as ciclosporin<br><br>8. Identification of factors related to failure<br><br>9. Routine measurement of AD<br><br>Plan to address : Prospective trials testing the clinical question followed by validation in independent population.<br><br>Priority : High.<br><br>Validation of different regimens:shorter or longer | | |

| Information extraite | Werfel 2021 (S2k-guideline update) | Agache 2021 (EAACI Biological Guidelines) | Lansang 2019 (Canadian Dermatology Association) | NICE 2018 (TA534) |
|---|---|---|---|---|
| | | intervals (‘pulse-wise’) rather than as a chronic (‘maintenance’) therapy (e.g. to prevent resistance)?<br><br>Plan to address : RCTs and real-life studies testing different approaches in terms of dose, duration and route.<br><br>Priority : Medium | | |
| Dupilumab (posologie ou niveaux sériques cibles) | The approved dosage (for subcutaneous injection) is 600 mg as an initial dose for adults and adolescents aged 12–17 with a body weight of ≥ 60 kg, and 400 mg for adolescents aged 12–17 with a body weight of < 60 kg. This is followed by 300 mg (resp. 200 mg for adolescents aged 12–17 with a body weight of < 60 kg) every other week as a maintenance dose. [Child admission > 6 years was not available.] | The recommended dose for adults and for adolescents > 60 kg is an initial dose of 600 mg, followed by 300 mg given every other week.<br><br>For adolescents < 60 kg the initial dose is 400 mg, followed by 200 mg given every other week.<br><br>For the 6–11 years of age children, dupilumab is given either every two weeks (200 mg) or four weeks (300 mg), based on weight, following an initial loading dose. | Dosing varies by body weight Q2W | The recommended dose, given by subcutaneous injection, is initially 600 mg (2×300-mg injections), followed by 300 mg given every other week. It can be used with or without topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas. "Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment". Some patients whose disease shows partial response may subsequently improve with continued treatment beyond 16 weeks. |

ACMTS : Agence canadienne des médicaments et des technologies de la santé; AD : atopic dermatitis; AE : adverse events; CHMP : Committee for Medicinal Products for Human Use; EAACI : European Academy of Allergy and Clinical Immunology; EADV; European Academy of Dermatology and Venerology; EASI : Eczema Area and Severity Index; ETFAD : European Task Force on Atopic Dermatitis; GDG : guidelines development group; IGA : Investigator´s Global Assessment; kg : kilogrammes; mg : milligrammes; QoL : quality of life; RCT : randomized clinical trials; SCORAD : SCORing Atopic Dermatitis.

# ANNEXE E

## Indications de paiement dans différentes provinces canadiennes

Une synthèse des informations relatives aux posologies recommandées et aux possibilités d'intensification de la posologie des médicaments biologiques concernés (médicament de référence et biosimilaires éventuels) pour les quatre provinces considérées a été réalisée dans les tableaux ci-dessous à des fins de concision et de pertinence.

### Gastroentérologie

| Province | Adalimumab | Infliximab | Védolizumab |
|---|---|---|---|
| Québec | **Maladie de Crohn chez l'adulte**<br>Induction :160 mg initialement et 80 mg à la semaine 2<br>Entretien : 40 mg aux 2 semaines.<br>Augmentation permise : 40 mg par semaine à partir de la 12e semaine de traitement, et ce, pour 3 mois. Renouvellement possible d'une durée maximale de 12 mois. | **Maladie de Crohn chez l'adulte**<br>Induction: maximum de 3 doses de 5 mg/kg.<br>Entretien : pas de dose maximale spécifiée. | **Maladie de Crohn chez l'adulte**<br>Induction : 300 mg administrées aux semaines 0, 2 et 6.<br>Entretien: 300 mg toutes les 8 semaines |
| | **Maladie de Crohn pédiatrique**<br>n/a | **Maladie de Crohn pédiatrique**<br>Induction: maximum de 3 doses de 5 mg/kg.<br>Entretien : pas de dose maximale spécifiée. | **Maladie de Crohn pédiatrique**<br>n/a |
| | **Colite ulcéreuse chez l'adulte**<br>Aucune dose maximale spécifiée | **Colite ulcéreuse chez l'adulte**<br>Aucune dose maximale spécifiée | **Colite ulcéreuse chez l'adulte**<br>300 mg aux semaines 0, 2 et 6, puis toutes les 8 semaines |
| Ontario | **Adult's Crohn disease**<br>Approvals will only allow for standard dosing for adalimumab. The recommended dosing regimen is 160mg at week 0; 80mg at week 2; followed by 40mg every two weeks.<br>Maintenance/Renewal: Approvals will only allow for standard dosing for adalimumab. The recommended dosing regimen is 40mg every 2 weeks. | **Adult's Crohn disease**<br>5mg/kg/dose at 0, 2 and 6 weeks followed by 5mg/kg/dose every 8 weeks. (Note: Higher doses up to 10mg/kg/dose may be considered in patients who have failed to respond to lower doses). | **Adult's Crohn disease**<br>300 mg administered at week 0, followed by 300mg at week 2, 300 mg at week 6, then 300 mg every 8 weeks thereafter. |

| Province | Adalimumab | Infliximab | Védolizumab |
|---|---|---|---|
| | **Ulcerative Colitis**<br>Approvals will only allow for standard dosing for adalimumab.<br>The recommended dosing regimen for induction is 160mg at week 0, followed by 80mg at week 2, then 40mg every other week.<br><br>Maintenance/Renewal: Approvals will only allow for standard dosing for adalimumab. The recommended dosing regimen is 40mg every other week. | **Ulcerative Colitis**<br>The recommended dosing regimen for induction is 5mg/kg/dose at 0, 2 and 6 weeks followed by 5mg/kg/dose every 8 weeks. | **Ulcerative Colitis**<br>**300 mg initially administered at week 0, followed by 300mg at week 2, 300mg at week 6, then 300 mg every 8 weeks thereafter.** |
| Alberta | **Maladie de Crohn**<br>Induction Dosing: maximum of one 160 mg dose of adalimumab per New Patient at Week 0 followed by an 80 mg dose at Week 2.<br><br>Maintenance Dosing: 40 mg dose of adalimumab no more often than every other week starting at Week 4 | **Crohn Disease**<br>Induction: 5 mg/kg dose of infliximab at each 0, 2 and 6 weeks (for a maximum total of three doses).<br>Maintenance Dosing: 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks. | **Crohn Disease**<br>Induction Dosing: 300 mg dose of vedolizumab at 0, 2 and 6 weeks (for a maximum total of three doses).<br>Maintenance Dosing: 300 mg dose of vedolizumab per patient every eight (8) weeks |
| | **Ulcerative Colitis**<br>Initial dose of 160 mg, followed by an 80 mg dose at week 2, then one 40 mg dose at weeks 4, 6 and 8.<br>Continued coverage may be approved for a dose of 40 mg every 2 weeks for a period of 12 months. | **Ulcerative Colitis**<br>Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.<br><br>Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks. | Ulcerative Colitis<br>Initial coverage may be approved for three doses of 300 mg of vedolizumab at 0, 2 and 6 weeks.<br><br>Following this assessment, continued coverage may be approved for a dose of 300 mg every 8 weeks. |
| Colombie-Britannique | **Crohn disease**<br>Induction: 12 week supply: 160 mg week 0, 80 mg week 2, then 40 mg weeks 4, 6, 8, and 10<br><br>Maintenance: 1 year: 40 mg every 2 weeks | **Crohn disease**<br>Induction: 3 doses: 5 mg/kg at 0, 2, and 6 weeks<br>Maintenance: 5 mg/kg every 8 weeks | **Crohn Disease**<br>Induction: 300 mg at 0, 2, and 6 weeks<br><br>Dose d'entretien: 1 year: 300 mg every 8 weeks |
| | **Ulcerative Colitis** | **Ulcerative Colitis** | **Ulcerative Colitis** |

**Rhumatologie**

| Biologique | Critère actuel (RAMQ) | Ontario | Alberta | Colombie-Britannique |
|---|---|---|---|---|
| **Polyarthrite rhumatoïde** | | | | |
| **Adalimumab** | 40 mg aux 2 semaines.<br>Augmentation possible à<br>40 mg par semaine après 12 semaines. | 40mg every two weeks | An initial 40 mg dose, followed by additional 40 mg doses at 2, 4, 6 and 8 weeks after the first dose.<br><br>40 mg every other week for a period of 12 months. | 40 mg every 2 weeks |
| **Étanercept** | 50 mg par semaine | 50mg per week or 25mg twice weekly | 50 mg per week | 50 mg weekly |
| **Infliximab** | 3mg/kg pour 3 doses.<br>Augmentation : 5 mg/kg après 3 doses ou à la 14e semaine | 3mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of 3mg/kg/dose every 8 weeks up to a maximum of six maintenance doses per year | 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion and every 8 weeks afterwards.<br>**[Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks].** | 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks; must be given in combination with a csDMARD: |
| **Rituximab** | Autorisation initiale :<br>2 perfusions de 1 000 mg chacune.<br>Renouvellement : maximum de 2 traitements. | One course of treatment is 1000 mg followed two weeks later by the second 1000mg dose. | 1000 mg of rituximab administered at 0 and 2 weeks (total of 2 - 1000 mg doses).<br><br>coverage for an additional two-dose course of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy. | Non remboursé pour cette indication |
| **Certolizumab pegol** | 400 mg aux semaines 0, 2 et 4, suivies de 200 mg toutes les 2 semaines ou de 400 mg toutes les 4 semaines. | 400mg at 0, 2 and 4 weeks followed by maintenance therapy of 200 mg every 2 weeks. For maintenance dosing, 400mg every 4 weeks may be considered | 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4 and every 4 weeks thereafter | 400 mg at 0, 2 and 4 weeks, followed |

| Biologique | Critère actuel (RAMQ) | Ontario | Alberta | Colombie-Britannique |
|---|---|---|---|---|
| **Golimumab** | Voie sous-cutanée : 50 mg par mois.<br>Voie intraveineuse : 2mg/kg aux semaines 0 et 4, puis à 2mg/kg toutes les 8 semaines. | Golimumab 50mg once a month | 50 mg per month | 50 mg SC once per month; must be given in combination with a csDMARD: |
| **Abatacept** | Voie intraveineuse : 10 mg/kg aux 2 semaines pour 3 doses, puis à 10 mg/kg toutes les 4 semaines.<br>Voie sous-cutanée : 125 mg par semaine. | Non inscrit | IV: 1000 mg/dose administered at 0, 2, 4, 8 and 12 weeks, then 1000 mg every 4 weeks<br><br>SC: a single IV loading dose of up to 1000 mg/dose followed by 125 mg subcutaneous injection within a day, then once-weekly 125 mg SC injections | Subcutaneous: 125 mg weekly Intravenous: weight 100 kg: 1000 mg at 0, 2 and 4 weeks, then every 4 weeks |
| **Sarilumab** | Dose maximale de 200 mg à toutes les 2 semaines. | 200 mg once every 2 weeks | 200 mg every 2 weeks | 200 mg every 2 weeks; also approved for 150 mg every 2 week dosing if needed |
| **Tocilizumab** | Voie intraveineuse : 8 mg/kg à toutes les 4 semaines.<br>Voie sous-cutanée : 162 mg par semaine | IV : 4mg/kg/dose once every 4 weeks followed by an increase to 8mg/kg/dose based on clinical response; even for individuals whose body weight is more than 100kg,<br>doses exceeding 800mg per infusion are not recommended<br><br>SC: < 100 kg weight, 162 mg every other week, followed by an increase to every week based on clinical response.<br>≥100 kg: 162 mg every week | IV: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks<br><br>SC: 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response and weight | Intravenous: 4 mg/kg (up to 800 mg) every 4 weeks Intravenous: 8 mg/kg (up to 800 mg) every 4 weeks with explanation:<br><br>Subcutaneous<br>- Patients less than 100 kg – starting dose of 162 mg every other week, followed by an increase to weekly based on clinical response.<br><br>- Patients at or above 100 kg – 162 mg weekly |

| Biologique | Critère actuel (RAMQ) | Ontario | Alberta | Colombie-Britannique |
|---|---|---|---|---|
| **Spondylarthrite ankylosante** | | | | |
| **Adalimumab** | maximum de 40 mg aux 2 semaines. | 40mg every 2 weeks | 40 mg dose every other week for a period of 12 months | 40 mg every 2 weeks |
| **Étanercept** | maximum de 50 mg par semaine. | 25 mg twice weekly or 50 mg once weekly | 50 mg per week, | 50 mg weekly |
| **Infliximab** | maximum de 5 mg/kg aux semaines 0, 2, 6 puis aux 6 à 8 semaines. | 3-5mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of up to 5mg/kg/dose every 6 to 8 weeks | An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion. | 3-5 mg/kg at 0, 2, and 6 weeks then every 8 weeks thereafter |
| **Certolizumab pegol** | 400 mg aux semaines 0, 2 et 4, puis 200 mg toutes les 2 semaines ou de 400 mg toutes les 4 semaines. | 400mg at 0, 2, and 4 weeks followed by maintenance therapy of 200 mg every 2 weeks or 400 mg every 4 weeks. | 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4 and then 400 mg per 4 weeks, | 400 mg at 0, 2, and 4 weeks, followed by 200 mg every other week or 400 mg every 4 weeks |
| **Golimumab** | Voie sous-cutanée : 50 mg par mois. | 50mg once a month | 50 mg per month, | 50 mg SC once per month |
| **Ixékizumab** | 80 mg toutes les 4 semaines. Pour les patients qui ont reçu au préalable un anti-TNFα, une dose initiale de 160 mg peut être autorisée. | Non remboursé pour cette indication | Non remboursé pour cette indication | Non remboursé pour cette indication |
| **Arthrite psoriasique** | | | | |
| **Adalimumab** | 40 mg aux 2 semaines | 40mg every two weeks | 40 mg dose every other week for a period of 12 months | 50 mg SC once per month |
| **Étanercept** | 50 mg par semaine | 25mg twice weekly or 50mg once weekly | 50 mg per week | 50 mg weekly |
| **Infliximab** | 5 mg/kg aux semaines 0, 2, 6 puis aux 6 à 8 semaines. | | 5 mg/kg at weeks 0, 2 and 6 and every 8 weeks afterwards. | 3-5 mg/kg at 0, 2, and 6 weeks then every 8 weeks thereafter |
| **Certolizumab pegol** | 400 mg aux semaines 0, 2 et 4, suivies de 200 mg toutes les 2 semaines ou de 400 mg toutes les 4 semaines. | 400 mg at week 0, 2, 4 then maintenance doses of 200 mg every 2 weeks or 400 mg every 4weeks | 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4, then 400 mg per 4 weeks | 400 mg at 0, 2, and 4 weeks, followed by 200 mg every other week or 400 mg every 4 weeks |
| **Golimumab** | Arthrite psoriasique modérée | 50mg once a month | 50 mg per month, | 50 mg SC once per month |

| Biologique | Critère actuel (RAMQ) | Ontario | Alberta | Colombie-Britannique |
|---|---|---|---|---|
| | ou grave, de forme rhumatoïde ou autre que rhumatoïde<br>Autorisation initiale : La demande initiale est autorisée pour une période maximale de 5 mois.<br>Posologie par voie sous-cutanée : Les autorisations sont données à raison de 50 mg par mois.<br>Renouvellement : Les demandes de poursuite de traitement sont autorisées pour une période maximale de 12 mois. | | | |
| **Sécukinumab** | Autorisation initiale : pour une période maximale de 5 mois. Maximum de 300 mg aux semaines 0, 1, 2, 3 et 4, puis à tous les mois.<br>Renouvellement : pour une période maximale de 12 mois. | 150mg sc at weeks 0, 1, 2, and 3 followed by monthly maintenance dosing starting at week 4. If a patient is an anti-TNFalpha inadequate responder and continues to have active psoriatic arthritis, consider using the 300 mg sc dose. For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis (i.e. 300 mg sc at weeks 0, 1, 2, and 3, followed by monthly maintenance dosing starting at week 4) | Four weekly doses of 150 mg of secukinumab at weeks 0, 1, 2 and 3, followed by 150 mg monthly dosing (or 300 mg for anti-TNF alpha inadequate responders) dose of secukinumab every month | 150 mg at weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing.<br><br>300 mg dosing considered if prior anti-TNF failure with ongoing active psoriatic arthritis, or if patient has coexistent moderate to severe plaque psoriasis |

| Biologique | Critère actuel (RAMQ) | Ontario | Alberta | Colombie-Britannique |
|---|---|---|---|---|
| **Ixékizumab** | 160 mg à la semaine 0, puis 80 mg toutes les 4 semaines. | Non remboursé pour cette indication | 160 mg dose (two 80 mg injections) at week 0, followed by 80 mg every 4 weeks | 160 mg at week 0, then 80 mg every 4 weeks thereafter |
| **Arthrite juvénile idiopathique ou polyarticulaire (arthrite rhumatoïde juvénile et arthrite chronique juvénile)** | | | | |
| **Abatacept** | 10 mg/kg aux 2 semaines pour 3 doses, puis à 10 mg/kg toutes les 4 semaines. | Pas de dose spécifiée | 10 mg/kg (maximum dose 1000 mg) at 0, 2, 4, 8, 12 and 16 weeks (total of six doses), then 10 mg/kg every 4 weeks | Posologie et doses maximales non précisées |
| **Adalimumab** | 20 mg toutes les 2 semaines pour les enfants dont le poids est supérieur à 10 kg mais inférieur à 30 kg.<br>40 mg toutes les 2 semaines pour les personnes dont le poids est supérieur à 30 kg. | a) 24 mg/m$^2$ (maximum 40 mg) every two weeks; OR<br>b) 20 mg every 2 weeks, if the Patient weighs less than 30 kg; OR<br>c) 40 mg every 2 weeks, if the Patient weighs more than 30 kg. | 24 mg per square meter body surface area (maximum dose 40 mg) every other week for 12 weeks | Posologie et doses maximales non précisées |
| **Étanercept** | Autorisation initiale : La demande initiale est autorisée pour une période maximale de 5 mois. Les autorisations pour l'arthrite idiopathique juvénile (arthrite rhumatoïde juvénile et arthrite chronique juvénile) modérée ou grave, de forme polyarticulaire ou systémique, sont données à raison de 0,8 mg/kg (dose maximale de 50 mg) par semaine.<br>Renouvellement : Les demandes de poursuite de traitement sont autorisées pour une période maximale de 12 mois. | The planned dosing regimen should be provided. The maximum recommended dose is 50mg once weekly. | 0.8 mg/kg/dose (maximum dose 50 mg) weekly | Posologie et doses maximales non précisées |
| **Infliximab** | 3 mg/kg pour 3 doses.<br>Augmentation : 5mg/kg après 3 doses ou à la 14e semaine. | Up to 6 mg/kg/dose at weeks 0, 2, and 6, followed by maintenance of up to 6 mg/kg/dose every 8 weeks | Non remboursé pour cette indication | Posologie et doses maximales non précisées |

| Biologique | Critère actuel (RAMQ) | Ontario | Alberta | Colombie-Britannique |
|---|---|---|---|---|
| **Tocilizumab** | Arthrite juvénile idiopathique systémique modérée ou grave<br><br>12 mg/kg à toutes les 2 semaines pour les enfants de moins de 30 kg, et de 8 mg/kg toutes les 2 semaines pour les enfants de 30 kg ou plus.<br><br>Arthrite juvénile (arthrite rhumatoïde juvénile et arthrite chronique juvénile) modérée ou grave<br><br>10 mg/kg à toutes les 4 semaines pour les enfants de moins de 30 kg, et de 8 mg/kg toutes les 4 semaines pour les enfants de 30 kg ou plus. | Recommended dosing for tocilizumab in combination with methotrexate:<br><br>IV dosing regimen:<br><br>a) 10 mg/kg every 4 weeks, if the Patient weighs less than 30kg; OR<br><br>b) 8 mg/kg every 4 weeks, if the Patient weighs more than or equal to 30kg.<br><br>SC dosing regimen: a) 162 mg once every 3 weeks if the Patient weighs less than 30kg<br><br>b) 162 mg once every 2 weeks if the Patient weighs 30kg or more | IV:<br>10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.<br><br>SC: one 162 mg every 2 to 3 weeks (based on weight) | Posologie et doses maximales non précisées |

## Dermatologie

| | Québec | Ontario | Alberta | Colombie-Britannique |
|---|---|---|---|---|
| **Psoriasis en plaques** | | | | |
| **Adalimumab** | 80 mg suivi de 40 mg aux 2 semaines | Initial 80mg administered subcutaneously at week 0, followed by 40mg subcutaneously given every other week starting at week 1, as approved by Health Canada.<br><br>If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended, and the physician should consider switching to an alternative biologic agent. | Initial coverage may be approved for an initial dose of 80 mg, followed by one 40 mg dose every other week beginning one week after the first dose | Initial dose 80 mg, then 40 mg week 1, then 40 mg every 2 weeks |
| **Étanercept** | Dose maximale de 50 mg deux fois par semaine | 50mg subcutaneous twice weekly for 12 weeks followed by maintenance therapy at 25-50mg subcutaneous once weekly as approved by Health Canada.<br><br>If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended and the physician should consider switching to an alternative biologic agent. | Initial coverage may be approved for up to 100 mg per week for 12 weeks followed by 50 mg per week for a period of 12 months | **Plaque Psoriasis**<br>50 mg twice weekly for 12 weeks and then 50 mg weekly to twice weekly |

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| **Infliximab** | 5 mg/kg aux semaines 0, 2, 6 puis aux 8 semaines | 5mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of 5mg/kg/dose every 8 weeks. | An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion and then 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months | 5 mg/kg at 0, 2 and 6 weeks and then every 8 weeks |
| **Brodalumab** | 210 mg aux semaines 0, 1 et 2 puis toutes les 2 semaines | 210mg subcutaneously at weeks 0, 1 and 2, and then every 2 weeks.<br><br>If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended and the physician should consider switching to an alternative biologic agent. | Non remboursé/en cours d'évaluation | Non inscrit |
| **Ixékizumab** | 160 mg à la semaine 0, 80 mg aux semaines 2, 4, 6, 8, 10, 12 puis 80 mg aux 4 semaines | 160mg at week 0, followed by 80mg subcutaneously at weeks 2, 4, 6, 8, 10, and 12, and then 80mg every 4 weeks.<br><br>If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended and the physician should consider switching to an alternative biologic agent. | Initial coverage may be approved for one 160 mg dose (two 80 mg injections) at weeks 0, followed by 80 mg (one injection) at Weeks 2, 4, 6, 8, 10, and 12 and then 80 mg every 4 weeks | 160 mg at week 0, then 80 mg at weeks 2, 4, 6, 8, 10 and 12 weeks and then every 4 weeks |

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| **Risankizumab** | 150 mg (soit deux injections de 75 mg) aux semaines 0 et 4, puis toutes les 12 semaines par la suite | 150mg subcutaneously at weeks 0 and 4, and then every 12 weeks. If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended, and the physician should consider switching to an alternative biologic agent. | 150 mg (two x 75 mg syringes) of risankizumab at weeks 0, 4 and 16 and then 150 mg every 12 weeks | 150 mg at week 0, 4 and 16 and then every 12 weeks |
| **Sécukinumab** | 300 mg aux semaines 0, 1, 2, 3, et 4, puis à tous les mois | 300mg subcutaneously at weeks 0, 1, 2 and 3, and then monthly starting at week 4.<br>If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended and the physician should consider switching to an alternative biologic agent. | Four weekly doses of 300 mg at weeks 0, 1, 2 and 3, followed by monthly dosing at weeks 4 and every month afterwards. | 300 mg at week 0, 1, 2, 3 and 4, then 300 mg monthly |
| **Ustékinumab** | 45 mg aux semaines 0 et 4 puis aux 12 semaines. Une dose de 90 mg peut être autorisée pour les personnes dont le poids corporel est supérieur à 100 kg. | 45mg to be administered at weeks 0, 4 and every 12 weeks thereafter. Alternatively, 90mg may be used in patients with a body weight of over 100kg. In patients weighing over 100kg, both the 45mg and 90mg doses were shown to be efficacious. However, 90mg was efficacious in a higher percentage of these patients. If the patient has not responded after 12 weeks of treatment, the physician should consider switching to an alternative biologic agent. | 45 mg (90 mg for patients weighing greater than 100 kg) at weeks 0, 4 and every 12 weeks | 45 mg or 90 mg (according patient's weight) at week 0, 4 and 16and then every 12 weeks |

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| **Dermatite atopique** | | | | |
| **Dupilumab** | Dose initiale maximale de 600 mg suivie d'une dose maximale de 300 mg toutes les deux semaines | Adults: An initial dose of 600 mg followed by 300 mg every other week. | Non inscrit | **Dermatite Atopique**<br>Non inscrit |

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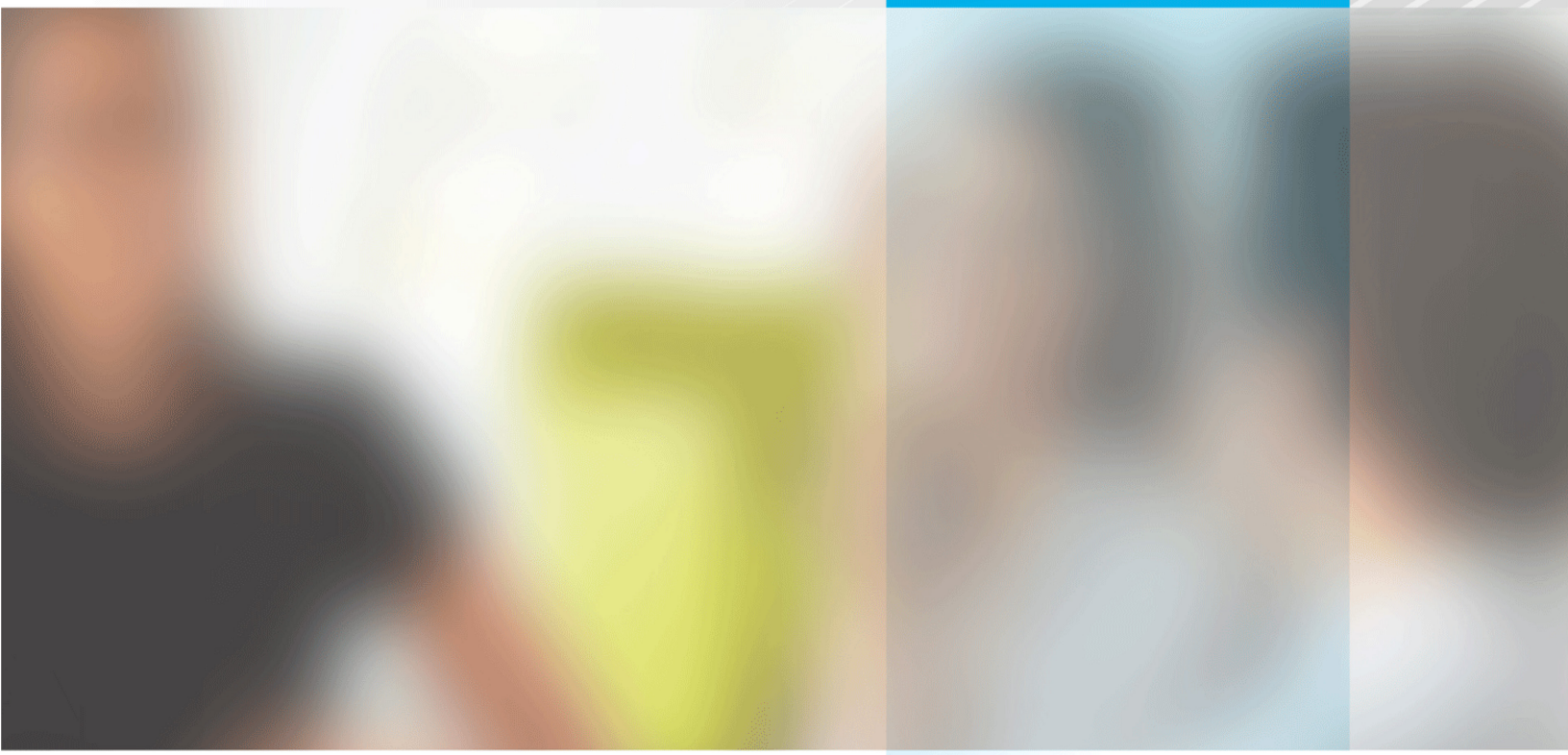


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