NIHB – Rheumatology Cheat Sheet (last updated 2018.05.07)

*Summary of Limited Use Updates for 2018:

Granulomatosis with Polyangiitis and Microscopic Polyangiitis: The criteria for induction of remission with Rituximab is set as a dose of 375 mg/m^2 body surface area, weekly x 4 weeks, for patients with severely active disease AND who have failed an adequate trial of cyclophosphamide OR who have a contraindication to cyclophosphamide.

Biosimilars:

- Infliximab: Inflectra is listed on the NIHB formulary since May 2017, and is provided for all new requests for infliximab in RA, PsA and AS. To encourage uptake of Inflectra, approvals will be valid indefinitely, with no renewal forms required.
- Etanercept: Brenzys was added to the formulary in September 2017, and Erelzi was added in February 2018. Either will be provided for all new requests for infliximab in RA, polyarticular JIA and AS. To encourage uptake, approvals will be valid indefinitely, with no renewal forms required.

Juvenile Idiopathic Arthritis:

- The dosing of adalimumab and etanercept has been updated.
- Response criteria are standardized across all agents as a 30% improvement in 3 of 6 clinical parameters (any 3 of number of active joints, number of joints with loss of range of motion, physician global assessment scale, patient or parent global assessment scale, CHAQ, ESR) AND that no more than one of these variables has worsened by >30%.

Rheumatoid Arthritis:

- Response criteria are standardized across all agents as a 20% improvement in 3 of 5 clinical parameters (tender and swollen joint counts, AND physician global, AND either patient global OR ESR/CRP.

Psoriatic Arthritis:

- NSAID requirement: The definition of refractory disease across all agents is now a trial of 2 different agents at maximum tolerated doses for a combined duration of 4 weeks.
- DMARD requirement: The definition of refractory disease has been changed to a requirement of ANY 2 of methotrexate, leflunomide, sulfasalazine or cyclosporine (i.e. the formulary no longer mandates a methotrexate trial, and gold has been deleted from the list of suggested DMARDs).
- Inflectra has been added to the formulary for this disease indication.
- Response criteria are standardized across all biologics to be based on the PsARC criteria (Improvement in at least two of the four PsARC criteria, one of which has to be joint tenderness or swelling score, with no worsening in any of the four criteria. A response in joint count is determined by a reduction of ≥ 30%. A response in the Physician or Patient Global Assessment scale is determined by a reduction of 1 point).
- Cosentyk (secukinumab) is now covered by NIHB effective April 12, 2018.

Ankylosing Spondylitis:

- NSAID requirement: The definition of refractory disease across all agents is now a trial of 2 different agents at maximum tolerated doses for a combined duration of 4 weeks.
- DMARD requirement for peripheral joint disease: The definition is now a trial of 8 weeks of methotrexate and 3 months of sulfasalazine.
- Inflectra has been added to the formulary for this disease indication.
- Response criteria are standardized across all biologics to be based on a BASDAI response (Improvement of at least 50% or 2 units)
- Cosentyk (secukinumab) is now covered by NIHB effective April 12, 2018.

Pain Management:

- Celebrex is an open access benefit. No prior approval is required.
- Opioids: the maximum morphine equivalents per day for non-cancer, non-palliative pain was decreased to a total of 400 mg morphine equivalents per day. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days). The Program will continue to evaluate this dose limit based on current Canadian opioid guidelines.

Important Links:

Click here for the Winter 2018 NIHB formulary: NIHB Winter 2018

NIHB Appeal Process
http://healthycanadians.gc.ca/health-system-systeme-sante/services/non-insured-health-benefits-services-sante-non-assures/appealing-decision-faire-appel/index-eng.php

Biologics for Inflammatory Arthritis Conditions

ANKYLOSING SPONDYLITIS

Biologic/Biosimilar	**Etanercept (Enbrel)**	**Etanercept (Brenzys)**	**Certolizumab Pegol**	**Adalimumab**	**Golimumab**	**Infliximab (Remicade)**	**Inflectra**	**Secukinumab**
Maximum Dose	50 mg weekly	50 mg weekly	400mg at weeks 0, 2, and 4, followed by 200mg every other week or 400mg every 4 weeks	40 mg q2weeks	50 mg monthly	Not on formulary for this indication	5 mg/kg at weeks 0, 2 and 6	150 mg Weeks 0, 1, 2, 3, 4 and then 150 mg monthly
Initial Criteria (1 year and prescribed by a rheumatologist)	BASDAI > 4 AND Refractory to a trial of 2 different NSAIDs at maximum tolerated doses for a combined total duration of at least 4 weeks	BASDAI > 4 AND Refractory to a trial of 2 different NSAIDs at maximum tolerated doses for a combined total duration of at least 4 weeks	BASDAI > 4 AND Refractory to a trial of 2 different NSAIDs at maximum tolerated doses for a combined total duration of at least 4 weeks	BASDAI > 4 AND Refractory to a trial of 2 different NSAIDs at maximum tolerated doses for a combined total duration of at least 4 weeks	BASDAI > 4 AND Refractory to a trial of 2 different NSAIDs at maximum tolerated doses for a combined total duration of at least 4 weeks	Not on formulary for this indication	BASDAI > 4 AND Refractory to a trial of 2 different NSAIDs at maximum tolerated doses for a combined total duration of at least 4 weeks	BASDAI > 4 AND Refractory to a trial of 2 different NSAIDs at maximum tolerated doses for a combined total duration of at least 4 weeks
Additional Initial Criteria for PERIPHERAL JOINT DISEASE	Refractory to weekly parenteral or oral methotrexate at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks AND Sulfasalazine 2g/day for at least 3 months	Refractory to weekly parenteral or oral methotrexate at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks AND Sulfasalazine 2g/day for at least 3 months	Refractory to weekly parenteral or oral methotrexate at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks AND Sulfasalazine 2g/day for at least 3 months	Refractory to weekly parenteral or oral methotrexate at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks AND Sulfasalazine 2g/day for at least 3 months	Refractory to weekly parenteral or oral methotrexate at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks AND Sulfasalazine 2g/day for at least 3 months	Not on formulary for this indication	Refractory to weekly parenteral or oral methotrexate at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks AND Sulfasalazine 2g/day for at least 3 months	Refractory to weekly parenteral or oral methotrexate at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks AND Sulfasalazine 2g/day for at

								least 3 months
Response Criteria	Improvement of at least 50% or 2 units in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score	To encourage uptake approvals will be valid indefinitely, with no renewal forms required.	Improvement of at least 50% or 2 units in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score	Improvement of at least 50% or 2 units in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score	Improvement of at least 50% or 2 units in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score	Not on formulary for this indication	To encourage uptake approvals will be valid indefinitely, with no renewal forms required.	Improvement of at least 50% or 2 units in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score

PSORIATIC ARTHRITIS

Biologic/Biosimilar	Etanercept	Certolizumab Pegol	Adalimumab	Golimumab	Infliximab (Remicade)	Inflectra	Apremilast	Secukinumab	Ustekinumab
Maximum Dose	50 mg weekly	400mg at weeks 0, 2, and 4, followed by 200mg every other week or 400mg every 4 weeks	40 mg q2weeks	50 mg monthly	Not on formulary for this indication	5 mg/kg, administered at 0, 2 and 6 weeks	Not on formulary for this indication	150 mg Weeks 0, 1, 2, 3, 4 and then 150 mg monthly If the patient is an anti-TNF inadequate responder and continues to have active PsA or has co-existent severe plaque psoriasis, 300 mg monthly will be considered	Not on formulary for this indication
Initial Criteria (1 year and prescribed by a rheumatologist)	At least two of the following: - 5 or more swollen joints; - if less than 5 swollen joints, at least one joint proximal to, or including wrist or ankle; - more than one joint with erosion on imaging study; - dactylitis of two or more digits; - tenosynovitis refractory to oral NSAIDs and steroid injections; - enthesitis refractory to oral NSAIDs and steroid injections (not required for	At least two of the following: - 5 or more swollen joints; - if less than 5 swollen joints, at least one joint proximal to, or including wrist or ankle; - more than one joint with erosion on imaging study; - dactylitis of two or more digits; - tenosynovitis refractory to oral NSAIDs and steroid injections; - enthesitis refractory to oral NSAIDs and steroid injections (not required for	At least two of the following: - 5 or more swollen joints; - if less than 5 swollen joints, at least one joint proximal to, or including wrist or ankle; - more than one joint with erosion on imaging study; - dactylitis of two or more digits; - tenosynovitis refractory to oral NSAIDs and steroid injections; - enthesitis refractory to oral NSAIDs and steroid injections (not required for	At least two of the following: - 5 or more swollen joints; - if less than 5 swollen joints, at least one joint proximal to, or including wrist or ankle; - more than one joint with erosion on imaging study; - dactylitis of two or more digits; - tenosynovitis refractory to oral NSAIDs and steroid injections; - enthesitis refractory to oral NSAIDs and steroid injections (not required for	Not on formulary for this indication	At least two of the following: - 5 or more swollen joints; - if less than 5 swollen joints, at least one joint proximal to, or including wrist or ankle; - more than one joint with erosion on imaging study; - dactylitis of two or more digits; - tenosynovitis refractory to oral NSAIDs and steroid injections; - enthesitis refractory to oral NSAIDs and steroid injections (not required for	Not on formulary for this indication	At least two of the following: - 5 or more swollen joints; - if less than 5 swollen joints, at least one joint proximal to, or including wrist or ankle; - more than one joint with erosion on imaging study; - dactylitis of two or more digits; - tenosynovitis refractory to oral NSAIDs and steroid injections; - enthesitis refractory to	Not on formulary for this indication

	Achilles tendon); - daily use of corticosteroids; - use of opioids > 12 hours per day for pain resulting from inflammation AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses for a combined total duration of 4 weeks AND a minimum of any two of the following: - Methotrexate weekly oral or parenteral at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks - leflunomide: 20mg daily for 10 weeks - sulfasalazine at least 2g daily for 3 months - cyclosporine OR AXIAL Disease with both of the following: BASDAI ≥ 4 AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses	Achilles tendon); - daily use of corticosteroids; - use of opioids > 12 hours per day for pain resulting from inflammation AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses for a combined total duration of 4 weeks AND a minimum of any two of the following: - Methotrexate weekly oral or parenteral at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks - leflunomide: 20mg daily for 10 weeks - sulfasalazine at least 2g daily for 3 months - cyclosporine OR AXIAL Disease with both of the following: BASDAI ≥ 4 AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses	Achilles tendon); - daily use of corticosteroids; - use of opioids > 12 hours per day for pain resulting from inflammation AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses for a combined total duration of 4 weeks AND a minimum of any two of the following: - Methotrexate weekly oral or parenteral at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks - leflunomide: 20mg daily for 10 weeks - sulfasalazine at least 2g daily for 3 months - cyclosporine OR AXIAL Disease with both of the following: BASDAI ≥ 4 AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses	Achilles tendon); - daily use of corticosteroids; - use of opioids > 12 hours per day for pain resulting from inflammation AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses for a combined total duration of 4 weeks AND a minimum of any two of the following: - Methotrexate weekly oral or parenteral at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks - leflunomide: 20mg daily for 10 weeks - sulfasalazine at least 2g daily for 3 months - cyclosporine OR AXIAL Disease with both of the following: BASDAI ≥ 4 AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses		Achilles tendon); - daily use of corticosteroids; - use of opioids > 12 hours per day for pain resulting from inflammation AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses for a combined total duration of 4 weeks AND a minimum of any two of the following: - Methotrexate weekly oral or parenteral at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks - leflunomide: 20mg daily for 10 weeks - sulfasalazine at least 2g daily for 3 months - cyclosporine OR AXIAL Disease with both of the following: BASDAI ≥ 4 AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses		oral NSAIDs and steroid injections (not required for Achilles tendon); - daily use of corticosteroids; - use of opioids > 12 hours per day for pain resulting from inflammation AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses for a combined total duration of 4 weeks AND a minimum of any two of the following: - Methotrexate weekly oral or parenteral at 20mg or greater (15mg or greater if patient is >65 years of age) for more than 8 weeks - leflunomide: 20mg daily for 10 weeks - sulfasalazine at least 2g daily for 3 months - cyclosporine	

	for a combined total duration of 4 weeks	for a combined total duration of 4 weeks	for a combined total duration of 4 weeks	for a combined total duration of 4 weeks		for a combined total duration of 4 weeks		OR AXIAL Disease with both of the following: BASDAI ≥ 4 AND Refractory to a trial of at least 2 different NSAIDs at maximum tolerated doses for a combined total duration of 4 weeks	
Response Criteria	Improvement in at least two of the four PsARC criteria, one of which has to be joint tenderness or swelling score, with no worsening in any of the four criteria. A response in joint count is determined by a reduction of ≥ 30%. A response in the Physician or Patient Global Assessment scale is determined by a reduction of 1 point.	Improvement in at least two of the four PsARC criteria, one of which has to be joint tenderness or swelling score, with no worsening in any of the four criteria. A response in joint count is determined by a reduction of ≥ 30%. A response in the Physician or Patient Global Assessment scale is determined by a reduction of 1 point.	Improvement in at least two of the four PsARC criteria, one of which has to be joint tenderness or swelling score, with no worsening in any of the four criteria. A response in joint count is determined by a reduction of ≥ 30%. A response in the Physician or Patient Global Assessment scale is determined by a reduction of 1 point.	Improvement in at least two of the four PsARC criteria, one of which has to be joint tenderness or swelling score, with no worsening in any of the four criteria. A response in joint count is determined by a reduction of ≥ 30%. A response in the Physician or Patient Global Assessment scale is determined by a reduction of 1 point.	Not on formulary for this indication	To encourage uptake of Inflectra, approvals will be valid indefinitely, with no renewal forms required.	Not on formulary for this indication	Improvement in at least two of the four PsARC criteria, one of which has to be joint tenderness or swelling score, with no worsening in any of the four criteria. A response in joint count is determined by a reduction of ≥ 30%. A response in the Physician or Patient Global Assessment scale is determined by a reduction of 1 point.	Not on formulary for this indication

JUVENILE IDIOPATHIC ARTHRITIS

Biologic/Biosimilar	**Etanercept**	**Adalimumab**	**Tocilizumab**	**Abatacept**	**Canakinumab**
Maximum Dose	0.8 mg/kg/week body surface area up to a maximum single dose of 50 mg weekly	24 mg/m^2 body surface area up to a maximum single dose of 40 mg every other week	Polyarticular JIA: Coverage is initially provided for 16 weeks at a dose of 10 mg/kg once every four weeks for children weighing < 30 kg and 8 mg/kg for children weighing > 30 kg. Systemic JIA: Coverage is initially provided for 16 weeks at a dose of 12 mg/kg once every two weeks for children weighing < 30 kg and 8 mg/kg for children weighing > 30 kg.	Coverage is initially provided for 16 weeks at a dose of 10 mg/kg for children <75 kg; 750 mg for children weighing 75 kg to 100 kg; and 1000 mg for children weighing >100kg.	Not on formulary for this indication
Initial Criteria (1 year and prescribed by a rheumatologist)	**POLYARTICULAR JIA** **Age ≥ 4 years** - ≥ 5 swollen joints; - ≥ 3 joints with limited range of motion and/or pain/tenderness; - Condition is refractory to an adequate trial of a therapeutic dose of methotrexate	**POLYARTICULAR JIA** **Age ≥ 2 years** - ≥ 5 swollen joints; - ≥ 3 joints with limited range of motion and/or pain/tenderness; - Condition is refractory to an adequate trial of a therapeutic dose of methotrexate.	**POLYARTICULAR JIA** **(Age ≥ 2 years)** - ≥ 5 swollen joints; - ≥ 3 joints with limited range of motion and/or pain/tenderness; - Condition is refractory to an adequate trial of a therapeutic dose of methotrexate **SYSTEMIC JIA (Age ≥ 2 years)** Responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate), due to intolerance or lack of efficacy.	**POLYARTICULAR JIA** **Age ≥ 6 years** - ≥ 5 swollen joints; - ≥ 3 joints with limited range of motion and/or pain/tenderness; - Condition is refractory to an adequate trial of a therapeutic dose of methotrexate.	Not on formulary for this indication
Response Criteria	30% improvement in 3 of 6 clinical parameters: • >30% reduction in the number of active joints • >30% reduction in the number of joints with loss	30% improvement in 3 of 6 clinical parameters: • >30% reduction in the number of active joints • >30% reduction in the number of joints with loss	30% improvement in 3 of 6 clinical parameters: • >30% reduction in the number of active joints • >30% reduction in the number of joints with loss of range of	30% improvement in 3 of 6 clinical parameters: • >30% reduction in the number of active joints • >30% reduction in the number of joints with loss of range of	Not on formulary for this indication

	of range of motion • >30% improvement in the Physician Global Assessment scale • >30% improvement in the Patient or Parent Global Assessment scale • >30% improvement in the Child Health Assessment Questionnaire (CHAQ) • >30% reduction in ESR AND • No more than one of these variables has worsened by greater than 30%	of range of motion • >30% improvement in the Physician Global Assessment scale • >30% improvement in the Patient or Parent Global Assessment scale • >30% improvement in the Child Health Assessment Questionnaire (CHAQ) • >30% reduction in ESR AND • No more than one of these variables has worsened by greater than 30%	motion • >30% improvement in the Physician Global Assessment scale • >30% improvement in the Patient or Parent Global Assessment scale • >30% improvement in the Child Health Assessment Questionnaire (CHAQ) • >30% reduction in ESR AND • No more than one of these variables has worsened by greater than 30%	motion • >30% improvement in the Physician Global Assessment scale • >30% improvement in the Patient or Parent Global Assessment scale • >30% improvement in the Child Health Assessment Questionnaire (CHAQ) • >30% reduction in ESR AND • No more than one of these variables has worsened by greater than 30%	

RHEUMATOID ARTHRITIS

Biologic/ Biosimilar/ tsDMARD	**Etanercept (Enbrel)**	**Etanercept (Brenzys)**	**Certolizumab Pegol**	**Adalimumab**	**Golimumab**	**Infliximab (Remicade)**	**Inflectra**	**Tocilizumab IV or SC***	**Tofacitinib**	**Rituximab**	**Abatacept IV or SC**
Maximum Dose	50 mg weekly	50 mg weekly	400mg at weeks 0, 2, and 4, followed by 200mg every other week or 400mg every 4 weeks	40 mg q2weeks	50 mg monthly	Initial dose of 3 mg/kg at 0, 2 and 6 weeks	Initial dose of 3 mg/kg at 0, 2 and 6 weeks	IV: Coverage is initially provided for 16 weeks at an initial dose of 4 mg/kg/dose every 4 weeks. Max dose 8 mg/kg to a maximum of 800 mg every 4 weeks. SC: <100 kg: Initial approval is for 162 mg every other week, can request up to a maximum of 162 mg every week (maximum 51 doses) >100 kg: 162 mg weekly (maximum 52 doses)	10 mg daily	1000 mg x 2 doses at 0 & 2 weeks	IV: Weeks 0, 2 and 4 then every 4 weeks 500 mg IV if <60 kg; 750 mg IV if 60-100 kg; 1000 mg IV if >100 kg SC: 1 IV dose load then 125 mg weekly
Initial Criteria (1 year and prescribed by a rheumatologist; for ≥ 18 years of age)	In combination with MTX or other DMARDs Refractory to - MTX (oral or parenteral at a dose ≥	In combination with MTX or other DMARDs Refractory to - MTX (oral or parenteral at a dose ≥	In combination with MTX or other DMARDs Refractory to - MTX (oral or parenteral at a dose ≥	In combination with MTX or other DMARDs Refractory to - MTX (oral or parenteral at a dose ≥	In combination with MTX or other DMARDs Refractory to - MTX (oral or parenteral at a dose ≥	As of May 1 2017, all new requests for infliximab will be provided with inflectra	In combination with MTX or other DMARDs Refractory to - MTX (oral or parenteral at a dose ≥	In combination with MTX or other DMARDs Refractory to - MTX (oral or parenteral at a dose ≥	In combination with MTX or other DMARDs Refractory to - MTX (oral or parenteral at a dose ≥	Refractory to - anti-TNF Recommended to be used in combination with MTX or	In combination with MTX or other DMARDs Refractory to - MTX (oral or parenteral at a dose ≥

	20mg weekly (≥ 15 mg weekly if patient is ≥ 65 years) for a minimum of 12 weeks of continuous treatment AND - MTX in combination with at least two other DMARDs, such as sulfasalazine and hydroxycholorquine, for a minimum of 12 weeks of continuous treatment OR, if the patient has a contraindication or intolerance to MTX and has failed: - Combination of at least two DMARDs, such as sulfasalazine, hydroxychloroquine, azathioprine, leflunomide, cyclosporine or gold, for a minimum of 12 weeks of continuous treatment	20mg weekly (≥ 15 mg weekly if patient is ≥ 65 years) for a minimum of 12 weeks of continuous treatment AND - MTX in combination with at least two other DMARDs, such as sulfasalazine and hydroxycholorquine, for a minimum of 12 weeks of continuous treatment OR, if the patient has a contraindication or intolerance to MTX and has failed: - Combination of at least two DMARDs, such as sulfasalazine, hydroxychloroquine, azathioprine, leflunomide, cyclosporine or gold, for a minimum of 12 weeks of continuous treatment	20mg weekly (≥ 15 mg weekly if patient is ≥ 65 years) for a minimum of 12 weeks of continuous treatment AND - MTX in combination with at least two other DMARDs, such as sulfasalazine and hydroxycholorquine, for a minimum of 12 weeks of continuous treatment OR, if the patient has a contraindication or intolerance to MTX and has failed: - Combination of at least two DMARDs, such as sulfasalazine, hydroxychloroquine, azathioprine, leflunomide, cyclosporine or gold, for a minimum of 12 weeks of continuous treatment	20mg weekly (≥ 15 mg weekly if patient is ≥ 65 years) for a minimum of 12 weeks of continuous treatment AND - MTX in combination with at least two other DMARDs, such as sulfasalazine and hydroxycholorquine, for a minimum of 12 weeks of continuous treatment OR, if the patient has a contraindication or intolerance to MTX and has failed: - Combination of at least two DMARDs, such as sulfasalazine, hydroxychloroquine, azathioprine, leflunomide, cyclosporine or gold, for a minimum of 12 weeks of continuous treatment	20mg weekly (≥ 15 mg weekly if patient is ≥ 65 years) for a minimum of 12 weeks of continuous treatment AND - MTX in combination with at least two other DMARDs, such as sulfasalazine and hydroxycholorquine, for a minimum of 12 weeks of continuous treatment OR, if the patient has a contraindication or intolerance to MTX and has failed: - Combination of at least two DMARDs, such as sulfasalazine, hydroxychloroquine, azathioprine, leflunomide, cyclosporine or gold, for a minimum of 12 weeks of continuous treatment		20mg weekly (≥ 15 mg weekly if patient is ≥ 65 years) for a minimum of 12 weeks of continuous treatment AND - MTX in combination with at least two other DMARDs, such as sulfasalazine and hydroxycholorquine, for a minimum of 12 weeks of continuous treatment OR, if the patient has a contraindication or intolerance to MTX and has failed: - Combination of at least two DMARDs, such as sulfasalazine, hydroxychloroquine, azathioprine, leflunomide, cyclosporine or gold, for a minimum of 12 weeks of continuous treatment	20mg weekly (≥ 15 mg weekly if patient is ≥ 65 years) for a minimum of 12 weeks of continuous treatment AND - MTX in combination with at least two other DMARDs, such as sulfasalazine and hydroxycholorquine, for a minimum of 12 weeks of continuous treatment OR, if the patient has a contraindication or intolerance to MTX and has failed: - Combination of at least two DMARDs, such as sulfasalazine, hydroxychloroquine, azathioprine, leflunomide, cyclosporine or gold, for a minimum of 12 weeks of continuous treatment	20mg weekly (≥ 15 mg weekly if patient is ≥ 65 years) for a minimum of 12 weeks of continuous treatment AND - MTX in combination with at least two other DMARDs, such as sulfasalazine and hydroxycholorquine, for a minimum of 12 weeks of continuous treatment OR, if the patient has a contraindication or intolerance to MTX and has failed: - Combination of at least two DMARDs, such as sulfasalazine, hydroxychloroquine, azathioprine, leflunomide, cyclosporine or gold, for a minimum of 12 weeks of continuous treatment	other DMARDs	20mg weekly (≥ 15 mg weekly if patient is ≥ 65 years) for a minimum of 12 weeks of continuous treatment AND - MTX in combination with at least two other DMARDs, such as sulfasalazine and hydroxycholorquine, for a minimum of 12 weeks of continuous treatment For IV only, ALSO: - Etanercept or Adalimumab or Golimumab or Certolizumab or Abatacept SC (minimum 12 week trial) OR, if the patient has a contraindication or intolerance to MTX and has failed: - Combination of at least two

											DMARDs, such as sulfasalazine, hydroxychloroquine, azathioprine, leflunomide, cyclosporine or gold, for a minimum of 12 weeks of continuous treatment
Response Criteria	20% improvement in 3 of 5 clinical parameters: >20% reduction in number of tender and swollen joints AND >20% improvement in physician global assessment scale AND >20% improvement in the patient global assessment scale OR >20% reduction in the acute phase as measured by	To encourage uptake approvals will be valid indefinitely, with no renewal forms required.	20% improvement in 3 of 5 clinical parameters: >20% reduction in number of tender and swollen joints AND >20% improvement in physician global assessment scale AND >20% improvement in the patient global assessment scale OR >20% reduction in the acute phase as measured by	20% improvement in 3 of 5 clinical parameters: >20% reduction in number of tender and swollen joints AND >20% improvement in physician global assessment scale AND >20% improvement in the patient global assessment scale OR >20% reduction in the acute phase as measured by	20% improvement in 3 of 5 clinical parameters: >20% reduction in number of tender and swollen joints AND >20% improvement in physician global assessment scale AND >20% improvement in the patient global assessment scale OR >20% reduction in the acute phase as measured by	20% improvement in 3 of 5 clinical parameters: >20% reduction in number of tender and swollen joints AND >20% improvement in physician global assessment scale AND >20% improvement in the patient global assessm	To encourage uptake of Inflectra, approvals will be valid indefinitely, with no renewal forms required.	20% improvement from baseline in swollen and tender joint counts, plus a 20% improvement in 2 of 5 baseline clinical parameters. • >20% reduction in number of tender and swollen joints; PLUS • >20% improvement in Physician Global Assessment scale; PLUS either • >20% improvement in Patient Global Assessment scale; OR • >20% reduction in the acute phase as measured by	20% improvement in 3 of 5 baseline clinical parameters: >20% reduction in number of tender and swollen joints AND >20% improvement in physician global assessment scale AND >20% improvement in the patient global assessment scale OR >20% reduction in the acute phase as	Assess between 20 and 24 weeks for: >20% reduction in number of tender and swollen joints AND >20% improvement in physician global assessment scale AND >20% improvement in the patient global assessment scale OR >20% reduction	Coverage beyond one year will be based on a 20% improvement in 3 of 5 clinical parameters: >20% reduction in number of tender and swollen joints AND >20% improvement in physician global assessment scale AND >20% improvement in the patient global assessment scale OR >20%

	ESR or CRP		ESR or CRP	ESR or CRP	ESR or CRP	ent scale OR >20% reduction in the acute phase as measured by ESR or CRP		ESR or CRP. SC – as per other agents	measured by ESR or CRP	in the acute phase as measured by ESR or CRP.	reduction in the acute phase as measured by ESR or CRP

Biologics for Granulomatosis with Polyangiitis or Microscropic Polyangiitis

Rituximab is provided at a dose of 375 mg/m^2 body surface area, weekly x 4 weeks, for induction of remission in patients with severely active disease AND who have failed an adequate trial of cyclophosphamide OR who have a contraindication to cyclophosphamide.

Biologics for Systemic Lupus Erythematosus

BELIMUMAB – is not a benefit

Limited Use Gout Therapy

FEBUXOSTAT
Prior approval required

For patients with symptomatic gout who have documented hypersensitivity to allopurinol

Limited Use Osteoporosis Therapy

Agent	Criteria
DENOSUMAB / PROLIA	For women with postmenopausal osteoporosis who have failed or have a contraindication to bisphosphonates due to hypersensitivity or abnormalities of the esophagus (e.g., esophageal stricture or achalasia); AND who have at least two of the following: • age >70 years • a prior fragility fracture • a bone mineral density (BMD) T-score ≤ -2.5

	Maximum dose covered is 60mg per 6-month period.
ZOLEDRONIC ACID	For the treatment of Paget's disease. Coverage will be granted for one dose per 12 month period; OR For women with postmenopausal osteoporosis who would otherwise be eligible for coverage of oral bisphosphonates, but who have a contraindication to bisphosphonates due to hypersensitivity or abnormalities of the esophagus (e.g., esophageal stricture or achalasia); AND who have at least two of the following: • age >70 years • a prior fragility fracture • a bone mineral density (BMD) T-score ≤ - 2.5.

Effective March 10, 2016, the following bisphosphonates became an open benefit:

Risedronate 5 mg, 30 mg, 35 mg and 150 mg Alendronate 5 mg, 10 mg, 40 mg and 70 mg Alendronate/vitamin D3

This change is intended to increase client access to medications for the treatment and prevention of osteoporosis and Paget disease.

Limited Use Pulmonary Arterial Hypertension Therapy

SILDENAFIL, TADALAFIL

Prior approval required and must be initiated by a Pulmonary Hypertension specialist.

Patients with World Health Organization (WHO) class III pulmonary artery hypertension (PAH), either idiopathic (i.e. primary) or associated with a congenital or systemic condition (e.g. connective tissue disease) and confirmed by right heart catheterization;

AMBRISENTEN (Maximum dose covered is 10 mg once daily): as above for patients with PAH, but who have failed to respond to sildenafil OR tadalafil; OR who have contraindications to sildenafil OR tadalafil.

BOSENTEN (Maximum dose covered is 125 mg twice daily): as above for patients with PAH, but who have failed to respond to sildenafil OR tadalafil; OR who have contraindications to sildenafil OR tadalafil.

Limited Use – Pediatrics Miscellaneous

ASA

ASA 80 mg tablets are a benefit to clients age 21 years and under to allow access for use in pediatric conditions (e.g. Kawasaki Syndrome).

Limited Use Analgesic Therapies

DICLOFENAC SODIUM 1.5% TOPICAL SOLUTION (PMS-Diclofenac DIN 02356783, Diclofenac topical DIN 02434571, Taro-Diclofenac DIN 02420988) and COMPOUND SOLUTIONS

Limited use benefit (prior approval required – pharmacist contacts DEC for approval).

For the treatment of osteoarthritis when:

a. Pain is inadequately controlled with acetaminophen AND a non-steroidal anti-inflammatory (NSAID) OR b. There is contraindication to acetaminophen and NSAID OR c. There is intolerance to acetaminophen and NSAID.

ACETAMINOPHEN, CAFFEINE CITRATE, CODEINE PHOSPHATE (T2, T3, EXDOL, ATASOL)

Limited use benefit (prior approval is not required).

For safety reasons NIHB has implemented a dose limit on acetaminophen. The limit accumulates against the amount of acetaminophen claimed to the program from plain acetaminophen and/or acetaminophen in combination with opioids such as codeine (i.e. Tylenol® #3) or oxycodone (i.e. Percocet®). A total of 360 grams of acetaminophen is permitted in a 100-day period, for a total daily dose of 3600mg/day.

ACETAMINOPHEN, CODEINE PHOSPHATE (ACETAMINOPHEN WITH CODEINE, ACET CODEINE 30, PROCET-30, RATIO-EMTEC-30, TRIATEC-30)

Limited use benefit (prior approval is not required).

For safety reasons NIHB has implemented a dose limit on acetaminophen. The limit accumulates against the amount of acetaminophen claimed to the program from plain acetaminophen and/or acetaminophen in combination with opioids such as codeine (i.e. Tylenol® #3) or oxycodone (i.e. Percocet®). A total of 360 grams of acetaminophen is permitted in a 100-day period,

for a total daily dose of 3600mg/day.

ACETAMINOPHEN, OXYCODONE HCL (PERCOCET, ENDOCET, OXYCODONE/ACET, RIVACOCET)

Limited use benefit (prior approval is not required).

For safety reasons NIHB has implemented a dose limit on acetaminophen. The limit accumulates against the amount of acetaminophen claimed to the program from plain acetaminophen and/or acetaminophen in combination with opioids such as codeine (i.e. Tylenol® #3) or oxycodone (i.e. Percocet®). A total of 360 grams of acetaminophen is permitted in a 100-day period, for a total daily dose of 3600mg/day.

ASA, OXYCODONE HCL (OXYCODAN);

Limited use benefit (prior approval is not required).

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented an opioid dose limit of 400 mg morphine equivalents per day for non-cancer, non-palliative pain. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days).

CODEINE MONOHYDRATE, CODEINE SULFATE TRIHYDRATE (CODEINE CONTIN CR)

Limited use benefit (prior approval required). For treatment of: a. - chronic pain and palliative care patients as an alternative to products containing codeine in combination with acetaminophen or ASA with or without caffeine, or b. - chronic pain and palliative care patients as an alternative to regular release codeine tablets when large doses are required.

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented an opioid dose limit of 400 mg morphine equivalents per day for non-cancer, non-palliative pain. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days).

CODEINE PHOSPHATE

Limited use benefit (prior approval is not required).

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented an opioid dose limit of 400 mg morphine equivalents per day for non-cancer, non-palliative pain. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days).

FENTANYL (FENTANYL, DURAGESIC)

Limited use benefit (prior approval required).

For the management of chronic pain in patients who are unresponsive or intolerant to at least one long-acting oral sustained released product, such as morphine, hydromorphone and oxycodone, despite appropriate dose titration and adjunctive therapy including laxatives and antiemetics.

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented an opioid dose limit of 400 mg morphine equivalents per day for non-cancer, non-palliative pain. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days).

HYDROMORPHONE HCL (HYDROMORPH, DILAUDID)

Limited use benefit. Prior approval required for controlled release capsules only. Regular release dosage forms are full benefits and do not require prior approval.

For treatment of moderate to severe chronic pain when other opioids such as morphine have been ineffective in controlling pain or in patients experiencing intolerable side effects.

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented an opioid dose limit of 400 mg morphine equivalents per day for non-cancer, non-palliative pain. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days).

METHADONE (METADOL)

Limited use benefit (prior approval required) with the following criteria:

Prescriber is registered with Health Canada and is eligible to prescribe methadone for the management of pain. AND For the management of moderate to severe cancer pain or chronic non-cancer pain, as an alternative to other opioids. OR, For the management of pain for palliative care patients. Pharmacists may only dispense a maximum supply of 30 days at one time.

MORPHINE HCL (DOLORAL, MORPHINE)

Limited use benefit (prior approval is not required).

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented an opioid dose limit of 400 mg morphine equivalents per day for non-cancer, non-palliative pain. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days).

MORPHINE SULFATE (M-ESLON, STATEX, MORPHINE SR, MS CONTIN SR)

Limited use benefit (prior approval required).

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented an opioid dose limit of 400 mg morphine equivalents per day for non-cancer, non-palliative pain. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days).

MORPHINE SULFATE (KADIAN)

• For the treatment of opioid dependence where methadone and Suboxone are not available or not appropriate OR • For the treatment of chronic pain.

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented an opioid dose limit of 400 mg morphine equivalents per day for non-cancer, non-palliative pain. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days).

OXYCODONE HCL (SUPEUDOL)

Limited use benefit (prior approval is not required).

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented an opioid dose limit of 400 mg morphine equivalents per day for non-cancer, non-palliative pain. This limit will be calculated based on the total dose of all opioids a client is receiving from NIHB within a 30-day period (i.e. 12000 morphine equivalents over 30 days).

SUBOXONE (BUPRENORPHINE)
Limited use benefit (prior approval required). Limited use benefit (prior approval required).

For the treatment of opioid dependence when: • The client must be 16 years or older. • In cases where the client lives in a remote or isolated location, confirmation is required that the community has the ability to support Suboxone administration. These supports include the safe daily witnessing, storage and handling of the Suboxone doses. After this confirmation, NIHB will approve the Suboxone for the client.

ACETAMINOPHEN

Limited use benefit (prior approval is not required).

For safety reasons NIHB has implemented a dose limit on acetaminophen. The limit accumulates against the amount of acetaminophen claimed to the program from plain acetaminophen and/or acetaminophen in combination with opioids such as codeine (i.e. Tylenol® #3) or oxycodone (i.e. Percocet®). A total of 360 grams of acetaminophen is permitted in a 100-day period, for a total daily dose of 3600mg/day.

Limited Use Criteria – Neuropathic Pain Agents

GABAPENTIN
Limited use benefit (prior approval is not required).

For safety reasons NIHB has implemented a dose limit on gabapentin. The limit accumulates against the amount of gabapentin claimed to the program. A total of 400 grams of gabapentin is permitted in a 100-day period, for a total daily dose of 4000mg/day.

PREGABALIN
Limited use benefit (prior approval required).For the treatment of neuropathic pain in patients who have failed to effectively treat their pain with a tricyclic antidepressant (TCA)

ORFor the treatment of neuropathic pain in patients who have a contraindication or intolerance with a TCA. The dose of pregabalin is limited to a maximum of 600 mg per day

Limited Use Criteria – Proton Pump Inhibitors (lansoprazole, omeprazole, pantoprazole, rabeprazole)

Prior approval not required.

The following PPI status change is primarily based on the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) report on optimal PPI therapy. The report concluded that:

•All PPIs are equally efficacious

•Double dose PPI is not necessary for initial therapy

•Double dose PPI is effective in H. Pylori eradication; however, treatment is not needed beyond 14 days.

PPI use has been associated with increased risk of hip fracture, community-acquired pneumonia and Clostridium difficile associated diarrhea. Although further study is needed to establish clinical significance, it is prudent to use the lowest dose and shortest duration of therapy required to control symptoms.

All proton pump inhibitors (open benefit and limited use (LU) PPIs) have a maximum quantity limit of 400 tablets/capsules per 180 day period. This quantity limit will be in effect for the entire class of PPIs.For example, if a patient fills 30 tablets of rabeprazole, then switch to 30 tablets of omeprazole, then switch to 30 capsules of lansoprazole, this will count as 90 PP tablets/capsules towards the quantity limit.

•Patients taking two rabeprazole 10mg tablets a day can be switched to one rabeprazole 20mg tablet a day to avoid reaching the quantity limitPatients taking two omeprazole 10mg tablets/capsules a day can be switched to one omeprazole 20mg tablet/capsule a day to avoid reaching the quantity limit

Patients with Zollinger Ellison Syndrome, Barrett's esophagus, erosive esophagitis and those who remain symptomatic on a single dose PPI will be eligible for additional doses above 400 tablets/capsules per 180 days through the prior approval process.

Previous Updates:
2016:

Methotrexate injections added to formulary! Here are the DINs:

Dose	DIN
7.5 mg	02422166
10 mg	02422174
15 mg	02422182
20 mg	02422190
25 mg	02422204