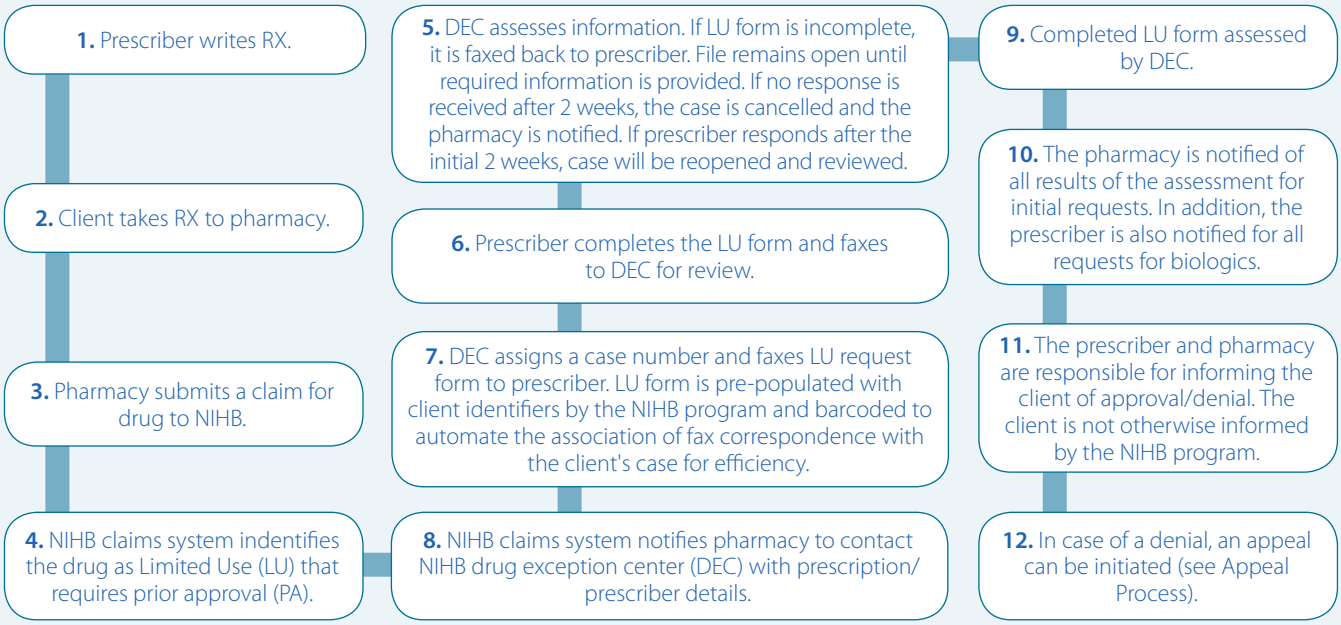
Top Ten Things Rheumatologists Should (And Might Not) Know About the NIHB Program

By Cheryl Barnabe, MD, FRCPC, MSc; Karen Fortin, BScPhm, ACPR; Susan Pierce, BScPharm, ACPR; Henry Averns, MB, ChB, FRCP (UK), FRCPC; and David Robinson, MD, MSc, FRCPC

The CRA, through the Optimal Care Committee (formerly Access to Care Committee), maintains a relationship with the First Nations and Inuit Health Branch of Health Canada to ensure that rheumatology patients covered under the Non-Insured Health Benefits (NIHB) Program have equitable access to necessary therapy. This *Top Ten* will review aspects of coverage relevant to rheumatologists.

1. The NIHB Program provides benefits for registered Indians (recognized by Indian and Northern Affairs Canada) or an Inuk recognized by Nunavut Tunngavik Incorporated, Inuvialuit Regional Corporation or Makivik Corporation. The NIHB Program does not cover benefits for First Nations without Treaty Status, nor Métis patients. As the payer of last resort, any coverage patients may have through private plans or provincial public agencies should be accessed first.
2. There are five types of benefits addressed by the NIHB Program: i) pharmacy benefits; ii) medical transportation; iii) vision care; iv) dental care; and v) medical supplies and equipment.
3. NIHB has recently joined the Pan-Canadian Pharmaceutical Alliance (PCPA) which will guide future formulary listings. For pharmacy benefits, the NIHB Formulary is published annually, and quarterly updates are provided. The available agents are listed at the following website: *www.hc-sc.gc.ca/fniah-spnia/nihb-ssna/provide-fournir/pharma-prod/med-list/index-eng.php*. The Optimal Care Committee maintains a regularly updated file of access criteria and response criteria on the CRA website: *https://rheum.ca/en/members/non_insured_health_benefits_nihb*. The other benefit areas are also found on the NIHB website: *www.canada.ca/en/health-canada/services/non-insured-health-benefits-first-nations-inuit.html*
4. Disease-modifying antirheumatic drugs (DMARDs, including pre-filled methotrexate syringes), corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs) and allopurinol are open benefits, do not require prior approval, and can be dispensed at the pharmacy visit. For Limited Use agents such as biologics and targeted synthetic DMARDs, a prior approval process is in place. Once the prescription is submitted to the pharmacy, a claim is initiated and this will generate the forms for completion that are faxed to the prescriber/physician. Once the forms are returned by the prescriber, the information provided on the forms is reviewed by a claims specialist, a dispensing history is checked, and a decision is made on whether the request is approved or denied. Figure 1 provides an overview of this approval process.
5. For access to Limited Use agents in rheumatology indications, the prescriber must be a rheumatologist. If the Limited Use criteria are met, approval for at least a one-year period is provided. The NIHB Formulary and the CRA "cheat sheet" contain the most updated information on initial access criteria, but Table 1 provides a general overview of the Limited Use criteria for different indications.
6. For renewal of Limited Use criteria, a new prescription is required, which will reinitiate the approval process. The NIHB Formulary and the CRA "cheat sheet" contain the most updated information on renewal criteria, but Table 2 provides a general overview of the Limited Use criteria for different indications. A one-year renewal period is provided, but for patients with a continuous demonstrated response to an agent, approval up to five years will be provided depending on the indication being treated.
7. An appeal process can be initiated when coverage for a benefit is denied. Appeals are submitted by the client, parent/legal guardian or representative of the client.Thus, some rheumatologists obtain written consent at the initiation of therapy to act as a representative. At the first level of appeal, a written and signed letter is submitted by mail indicating the client information (Indian/Inuit registration number

Figure 1. NIHB Limited Use Drug Approval Process



RX: Prescription; DEC: Drug Expression Centre.
Chart adapted from: https://rheum.ca/images/documents/NIHB_process_for_CRA_April_2017.pdf

Table 1.

Initial Access Criteria

Rheumatoid Arthritis	Refractory to methotrexate, and methotrexate in combination with at least two other DMARDs for at least 12 weeks. If there is a contraindication or intolerance of methotrexate, then a combination of at least two other DMARDs must be tried.
Psoriatic Arthritis	For peripheral disease: *At least two of the following features are present:* Five or more swollen joints or at least one joint proximal to or including wrist or ankle; erosion; dactylitis of two or more digits, refractory tenosynovitis or enthesitis to oral NSAIDS and injections excluding the Achilles tendon, + daily steroid use, opioids > 12 hours per day for inflammatory pain. Refractory or intolerant to NSAIDs (trial of two different NSAIDs for a combined total of 4 weeks), plus a minimum of two DMARDs. For axial disease: Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4 AND refractory or intolerant to NSAIDs (trial of two different NSAIDs for a combined total of 4 weeks).
Anklylosing Spondylitis	For axial disease: BASDAI > 4 and refractory or intolerant to NSAIDs (trial of two different NSAIDs for a combined total of 4 weeks). For peripheral disease: BASDAI > 4 and refractory or intolerant to NSAIDs (trial of two different NSAIDs for a combined total of 4 weeks) and trials of both methotrexate and sulfasalazine (doses and durations of trials specified in the formulary).
Polyarticular Juvenile Idiopathic Arthrits (JIA)	*All of the following features are present:* Five or more swollen joints, three or more joints with limited range of motion (ROM) and/or pain/tenderness, and refractory to methotrexate.
Systemic JIA	Inadequate response to NSAIDs and systemic steroids due to intolerance or lack of efficacy.

Table 2.

Renewal Criteria

Rheumatoid Arthritis	> 20% reduction in the number of tender and swollen joints AND > 20% improvement in physician global and patient global scores OR > 20% reduction in the erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP).
Psoriatic Arthritis	Improvement in at least two of the four psoriatic arthritis response criteria (PsARC): tender joints, swollen joints, Physician Global Assessment, or Patient Global Assessment; one of which has to be joint tenderness or swelling score; and 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.
Ankylosing Spondylitis	Improvement of at least 50% or 2 units in the BASDAI score.
Polyarticular Juvenile Idiopathic Arthritis	30% improvement in 3 of 6 clinical parameters of: active joints, joints with loss of range of motion, ESR, Physician Global, Patient/Parent Global, CHAQ
Systemic JIA	30% improvement in 3 of 6 clinical parameters of active joints, joints with loss of range of motion, ESR, Physician Global, Patient/Parent Global, CHAQ
Vasculitis	Case by case review

and date of birth); name and address of the prescriber; the pharmacy where the medication was denied; the condition for which the medication is being requested; the diagnosis, prognosis and alternatives tried; relevant diagnostic test results, and other supporting information such as case notes. Level 1 appeals are reviewed by the manager of the Pharmacy Policy Development Division; Level 2 appeals are reviewed by the Director for the Benefit Management and Review Services Division; and Level 3 appeals by the NIHB Director General. Details on the appeal process are found at: *http://healthycanadians.gc.ca/health-system-systeme-sante/services/non-insured-health-benefits-services-sante-non-assures/appealing-decision-faire-appel/index-eng.php*. Appeals for vision care, medical transportation, medical supplies and equipment and mental health counselling are submitted to the NIHB Program in the province or territory of residence.

8. Coverage for osteoarthritis management includes intra-articular steroid preparations. Intra-articular hyaluronic acid preparations are only approved as an Exception for osteoarthritis of the knee when other treatments have failed. Topical NSAIDs (Pennsaid 1.5% and compounded) are covered but a Limited Use form will need to be completed. Assistive devices (canes, braces, *etc.*) are provided on a limited provision basis, and providers must submit claims and require receive approval for the devices before they are dispensed.
9. Recently, an opioid equivalent limitation has been set in place in the program. Oral adjunctive pain treatments that are open benefit include serotonin-specific reuptake inhibitors (SSRIs), gabapentin, duloxetine, tricyclic antidepressants and anticonvulsants, such as valproate and topiramate. Pregabalin and nabilone are Limited Use therapies.
10. If you are having difficulty with any aspect of NIHB Program coverage, the number for the Drug Exception Centre is 1-800-580-0950 (Press 2 to speak with a supervisor). Patients may also contact their NIHB Navigator to assist with the process.

Cheryl Barnabe, MD, FRCPC, MSc
Associate Professor,
University of Calgary
Calgary, Alberta

On behalf of Karen Fortin, BScPhm, ACPR; Susan Pierce, BScPharm, ACPR; Henry Averns, MB ChB, FRCP (UK), FRCPC; and David Robinson, MD, MSc, FRCPC