NIHB Recent Listings for CRA – Updated August 2019

Drug	Listing Status	Criteria	Listing Date
Tofacitinib (Xeljanz) XR version for 11 mg OD		Tofacitinib (Xeljanz) 5 mg BID was previously approved, and now the XR version for 11 mg OD is covered as well.	August 26, 2019
Erelzi		Effective April 29, 2019 Erelzi was listed for Psoriatic Arthritis (PsA). Erelzi is the only biosimilar approved for this indication and reimbursed. Criteria would be the same as for other anti-TNF in PsA. To encourage uptake of biosimilars, there will be no requirement for renewal forms as long as the patient remains on Erelzi.	April 29, 2019
Renflexis	Limited Use Benefit	Effective April 17, 2019 Renflexis (infliximab biosimilar) was listed for rheumatologic indications including rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS), as well as for other Health Canada-approved indications. Renflexis (or Inflectra) will be preferred therapy for infliximab-naïve patients. The limited use criteria are the same criteria used for other biologics for the treatment of RA, PsA and AS. To encourage uptake of biosimilars, there will be no requirement for renewal forms when Renflexis is used.	April 17, 2019
Actemra	Limited Use Benefit	Effective April 16, 2019 Actemra (tocilizumab) subcutaneous injection was listed for giant cell arteritis (GCA), added to the previous listing for rheumatoid arthritis. **Limited Use Criteria** **Giant Cell Arteritis:** Coverage is limited to 52 weeks per treatment course at a dose of 162 mg sc weekly. GCA criteria: patient has been diagnosed with new-onset or relapsing active giant cell arteritis; and the patient is receiving moderate- to high-dose oral corticosteroids (equivalent to prednisone 20 mg to 60 mg daily). Treatment can be repeated if relapse occurs.	April 16, 2019

Taltz	Limited Use Benefit	Effective March 12, 2019 Taltz (ixekizumab) was listed for psoriatic arthritis (PsA), added to the previous listing for psoriasis. The limited use criteria listed below are the same criteria used for other biologics for the treatment of PsA. **Limited Use Criteria** **Psoriatic arthritis:** Coverage is provided for an initial period of one year at a dose of 160 mg at Week 0, followed by 80 mg every 4 weeks. For psoriatic arthritis patients with coexistent moderate-to-severe psoriasis, coverage is provided for psoriasis dosing: 160 mg at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks. For psoriatic arthritis patients with coexistent mild plaque psoriasis, coverage is provided for psoriatic arthritis dosing: 160 mg at Week 0, followed by 80 mg every 4 weeks. *For peripheral disease*: At least 2 of the following features are present: 5 or more swollen joints or at least one joint proximal to or including wrist or ankle; erosion; dactylitis of 2 or more digits, refractory tenosynovitis or enthesitis refractory to oral NSAIDS and steroid injections excluding the Achilles tendon), daily steroid use, opioids >12 hrs per day for inflammatory pain. Refractory or intolerant to NSAIDs (trial of 2 different NSAIDs for a combined total of 4 weeks), plus a minimum of 2 DMARDs. *For axial disease*: BASDAI≥4 AND refractory or intolerant to NSAIDs (trial of 2 different NSAIDs for a combined total of 4 weeks). Coverage beyond one year will be based on improvement in at least 2 of 4 Psoriatic Arthritis Response Criteria (PsARC) listed below, one of which has to be joint tenderness or swelling score, with no worsening in any of the four criteria. Renewal criteria list: number of tender joints; number of swollen joints; Physician Global Assessment scale score (0-10 point scale, 0 = remission, 10 = most severe); Patient Global Assessment scale score (0-5 point scale, 0 = least severe, 5 = most severe). A response in joint count is determined by a reduction of ≥ 30%. A response in the Physician or Patient Global Assessment scale score is determined by a reduction of 1 point.	March 12, 2019
