Ontario Rheumatology Association

Ontario Public Drug Programs

Inflectra (infliximab) Frequently Asked Questions

1. What is the funding status of Inflectra (infliximab)?
Effective February 25 2016, Inflectra (infliximab) will be added to the Ontario Drug Benefit (ODB) Formulary as a Limited Use (LU) benefit for the treatment of severe rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.

2. What are the Limited Use Criteria for Inflectra (infliximab)?

Reason For Use (RFU) Code and Clinical Criteria

A. Rheumatoid Arthritis (Code 468)
For the treatment of rheumatoid arthritis (RA) in patients who have severe active disease (≥ 5 swollen joints and rheumatoid factor positive and/or, anti-CCP positive, and/or radiographic evidence of rheumatoid arthritis) and have experienced failure, intolerance, or have a contraindication to adequate trials of disease-modifying anti-rheumatic drugs (DMARDs) treatment regimens, such as one of the following combinations of treatments:

A. i) Methotrexate (20 mg/week) for at least 3 months, AND ii) leflunomide (20 mg/day) for at least 3 months, in addition to iii) an adequate trial of at least one combination of DMARDs for 3 months; OR

B. i) Methotrexate (20 mg/week) for at least 3 months, AND ii) leflunomide in combination with methotrexate for at least 3 months; OR

C. i) Methotrexate (20mg/week), sulfasalazine (2 g/day) and hydroxychloroquine (400mg/day) for at least 3 months. (Hydroxychloroquine is based by weight up to 400 mg per day.)

Maintenance/Renewal:
After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For renewals beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect. Therapy must be prescribed by a rheumatologist or a physician with expertise in rheumatology.

The recommended dosing regimen is 3 mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of 3 mg/kg/dose every 8 weeks up to a maximum of six maintenance doses per year. LU Authorization Period: 1 year

B. Ankylosing Spondylitis (Code 469)

For the treatment of ankylosing spondylitis (AS) in patients who have severe active disease (confirmed by radiographic evidence*) with:

- Age of disease onset ≤ 50 years; AND
- Low back pain and stiffness for greater than 3 months that improves with exercise and which are not relieved by rest; AND
- Failure to respond to or documented intolerance to adequate trials of 2 non-steroidal anti-inflammatory drugs (NSAIDs) for at least 4 weeks each; AND
- Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥ 4 for at least 4 weeks while on standard therapy.

*Radiographic evidence demonstrating the presence of 'SI joint fusion' or 'SI joint erosion' on x-ray or CT scan, or MRI demonstrating the presence of 'inflammation' or 'edema' of the SI joint.

Maintenance/Renewal:

After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 50% reduction in BASDAI score or ≥ 2 absolute point reduction in BASDAI score. For funding beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a physician with expertise in rheumatology.

The recommended dosing regimen is 3 to 5mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of up to 5mg/kg/dose every 6 to 8 weeks.

LU Authorization Period: 1 year.

C. Psoriatic Arthritis (Code 470)

For the treatment of psoriatic arthritis in patients who have severe active disease (≥ 5 swollen joints and radiographic evidence of psoriatic arthritis) despite: i) treatment with methotrexate (20 mg/week) for at least 3 months; AND ii) one of leflunomide (20 mg/day) or sulfasalazine (1g twice daily) for at least 3 months.

If the patient has documented contraindications or intolerances to methotrexate, then only one of leflunomide (20 mg/day) or sulfasalazine (1 g twice daily) for at least 3 months is required.

Maintenance/Renewal:
After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For funding beyond the second year, the patient must have objective evidence of preservation of treatment effect. Therapy must be prescribed by a rheumatologist or a physician with expertise in rheumatology.

The recommended dosing regimen is 5 mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of 5 mg/kg/dose every 8 weeks.

LU Authorization Period: 1 year.

D. Plaque Psoriasis (Code 471)
For the treatment of severe* plaque psoriasis in patients 18 years of age or older who have experienced failure, intolerance, or have a contraindication to adequate trials of several standard therapies**.

Claims for the first 6 months must be written by a dermatologist.

Monitoring of patients is required to determine if continuation of therapy beyond 12 weeks is required.

Patients not responding adequately at 12 weeks should have treatment discontinued.

* Severe plaque psoriasis:
- Body Surface Area (BSA) involvement of at least 10%, or involvement of the face, hands, feet or genital regions, AND
- Psoriasis Area and Severity Index (PASI) score of at least 10 (not required if there is involvement of the face, hands, feet or genital regions), AND
- Dermatology Life Quality Index (DLQI) score of at least 10.

** Failure, intolerance or contraindication to adequate trials of standard therapies:
- 6 month trial of at least 3 topical agents including vitamin D analogues and steroids,
  AND
- 12 week trial of phototherapy (unless not accessible), AND
- 6 month trial of at least 2 systemic, oral agents used alone or in combination
- Methotrexate 15-30mg per week
- Acitretin (could have been used with phototherapy)
- Cyclosporine

Maintenance/Renewal:
After 3 months of therapy, patients who respond to therapy should have:

- At least a 50% reduction in PASI, AND
- at least a 50% reduction in BSA involvement, AND
- at least a 5 point reduction in DLQI score

The recommended dosing regimen is 5 mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of 5mg/kg/dose every 8 weeks.

LU Authorization Period: 1 year.

3. What is difference between Inflectra (infliximab) and Remicade (infliximab)?

Inflectra and Remicade are both infliximab products. Infliximab is an anti-inflammatory medicine that belongs to the class of drugs called biological response modifiers. Inflectra is approved by Health Canada as a subsequent entry biologic (SEB) to Remicade. Inflectra and Remicade are manufactured and marketed by different companies.

Please refer to Health Canada's website for further details on SEBs.

4. Are patients with existing Exceptional Access Program (EAP) approval for Remicade (infliximab) required to switch to Inflectra (infliximab)?

No. Patients who have an existing Exceptional Access Program (EAP) approval for Remicade (infliximab) can continue to receive Remicade (infliximab) for the duration of the EAP approval period. The ministry will also consider EAP renewal requests for Remicade (infliximab) for patients with existing EAP approvals.

The Limited Use (LU) criteria for Inflectra (infliximab) will apply to both new and existing patients with severe rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.

Claims for Inflectra (infliximab) will be reimbursed under the ODB program when prescribed in accordance with the LU criteria and accompanied by a valid, fully completed prescription with the appropriate LU documentation (RFU code).

5. Will the ministry consider new requests for Remicade (infliximab) reimbursement under the Exceptional Access Program, for the treatment of severe rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis?

The ministry will no longer accept new requests for Remicade (infliximab) under the Exceptional Access Program for the treatment of severe rheumatoid arthritis, ankylosing

spondylitis, psoriatic arthritis, and plaque psoriasis. EAP requests for other indications may be considered.

6. Will the ministry consider requests for Remicade reimbursement under the Exceptional Access Program for patients who do not respond to Inflectra (infliximab), or are intolerant to Inflectra (infliximab)?

The ministry will not consider requests for Remicade (infliximab) reimbursement for patients who do not respond to Inflectra (infliximab), or are intolerant to Inflectra (infliximab) under any program. The physician may wish to consider other therapeutic options.

7. Is Inflectra (infliximab) currently funded for indications other than rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis?

Inflectra (infliximab) is currently listed on the ODB Formulary as a Limited Use (LU) benefit for the following four indications: rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. At this time, there is no reimbursement for Inflectra (infliximab) for any other indications either as an LU benefit or through the Exceptional Access Program.

8. How should pharmacies submit claims for Inflectra (infliximab)?

Pharmacies should be submitting claims using the drug identification number (DIN) of the product and the appropriate reason for use code. If the pharmacy is compounding Inflectra (infliximab) the pharmacy should consult the extemporaneous policy and submit the DIN of the product with the appropriate compounding code.

For pharmacies:
Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For all other Health Care Providers and the Public:
Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282

OTHER ISSUES:

1) All new starts for infliximab who meet criteria under EAP will receive Inflectra for Adult RA, AS, PSA, PSO.

    a. Subpopulations: New starts for juvenile idiopathic arthritis (JIA) – all subtypes and both adult and pediatric Uveitis (non-

infectious ocular inflammatory disease) who meet EAP criteria will continue to receive Remicade.

b. A patient who is on Remicade prior to February 25, 2016 and who meet EAP criteria will continue with Remicade. At this time there is no mandatory switching.

c. Clients age <65 previously on Remicade paid for by private insurance who turn 65 and meet EAP criteria are eligible to continue with Remicade, without a mandatory switch to Inflectra.

d. Dosing in Rheumatoid Arthritis with Inflectra: patients that require dosing > 3mg/kg and/or treatment intervals as often as every 4 weeks, will be considered by EAP.

2) How to Enroll a patient into the INFLECTRA Patient Support Program

a. Complete the INFLECTRA Patient Assistance Program Enrolment Form (see attached)
b. Place the LU code on in the Physician Prescribing Section in the Enrolment Form
c. Fax into the INFLECTRA Patient Assistance Program at 1-844-295-0219 or contact your INFLECTRA Navigator

3) The ORA position statement for SEBs is housed on the ORA Website http://ontariorheum.ca/home/welcome. Do check the ORA website on a regular basis!

4) The ORA in conjunction with the Inflectra PSP will help with any issues regarding access to infusion clinics. Please email questions or concerns to drkarasik@bellnet.ca prior to June 1, 2016 and to henry@rheumors.com starting June 1, 2016.