Health and Community Services

Infliximab (Remicade 100mg Powder for Injection)

Rheumatoid arthritis (RA):

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

or

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 24 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Maximum Dosage Approved:
  - Infliximab (Remicade): 3mg/kg/dose at 0, 2 and 6 weeks, then every 8 weeks thereafter.

Ankylosing Spondylitis:

- For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score ≥ 4 on 10 point scale) who:

    - have axial symptoms* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation or in whom NSAIDs are contraindicated

OR

    - have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

* Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease, do not require a trial of NSAIDs alone.

Must be prescribed by a rheumatologist or internist.

Approval will be for a maximum of 6 months.

- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
    - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score;

OR

- patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work").

Approvals will be for a maximum dose of 5mg/kg at 0, 2, 6 weeks and then every 6 to 8 weeks thereafter and will NOT be reimbursed in combination with other anti-TNF agents.

To facilitate this process specific **RA Medications Special Authorization Forms** have been developed and can be found at:

http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Crohn's disease:

For the treatment of patients with moderate or severe active disease* with contraindications to or not achieving remission with glucocorticosteroids **AND** immunosuppressive therapy.

- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) score.

Initial approval, 3 infusions of infliximab 5mg/kg at week 0, 2 & 6.

Continued coverage dependent on evidence of response using criteria such the 100 point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less or a decrease in score of 4 or more.

Coverage can be reassessed annually dependent on evidence of response (as outlined above).

The maximum approved dose is 5mg/kg every 8 weeks.

* Patients very ill & not candidates for surgery may qualify for immediate infliximab induction therapy, as they may require a more rapid response.

Concurrent use of biologics not approved.

Written request by Gastroenterogist or physician with a specialty in gastroenterology.

To facilitate this process, a specific **Anti-TNF agents for Crohn's disease Special Authorization Form** has been developed and can be found at:

http://www.health.gov.nl.ca/health/prescription/crohns_meds.pdf

Chronic Plaque Psoriasis (PsO):

For patients with severe, debilitating PsO who meet all of the following criteria:

- Body Surface Area (BSA) involvement of > 10% and/or significant involvement of the face, hands, feet or genital region.
- Failure to respond to, contraindications to or intolerant of methotrexate and cyclosporine.
- Failure to respond to, intolerant of or unable to access phototherapy.

Coverage will be initially approved for 12 weeks. Continuation of therapy beyond 12 weeks will depend on response. Patients not responding adequately at 12 weeks should have treatment discontinued with no further treatment recommended.

An adequate response is defined as either:

- A 75% reduction in the Psoriasis Area and Severity Index (PASI) score (PASI 75) from when treatment started, or
- A 50% reduction in the PASI score (PASI 50) and a 5 point reduction in DLQI (Dermatology Life Quality Index) from when treatment started.

Written request of dermatologist only.

Two biologicals cannot be given concurrently.

Dosage restricted to Infliximab 5mg/kg ay 0, 2 and 6 weeks then every 8 weeks.

To facilitate this process a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at: http://www.health.gov.nl.ca/health/prescription/chronic_plaque_psoriasis_meds_coverage_request.pdf

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