

Questions and Answers

Change in Listing Status

Enbrel (etanercept), Humira (adalimumab) and Stelara (ustekinumab)

1. What is the change in listing status for Enbrel and Humira?

Currently these products are listed as General Benefit products with therapeutic notes and distinct PINs. When the changes become effective, Enbrel and Humira will become Limited Use benefits for the treatment of severe plaque psoriasis. The Limited Use criteria will be the same as the current therapeutic notes which are:

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.

**Definition of 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

***Definition of 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*

LU Authorization Period: 1 year

2. What is the change in listing status for Stelara?

Stelara is not currently funded through the Ontario Drug Benefit Program but will be listed as a Limited Use product according to the same Limited Use criteria noted above for Enbrel and Humira.

3. Are there any other related changes?

The PINs associated with the current listing of Enbrel and Humira will no longer be required once the change to Limited Use becomes effective.

A new format of Enbrel, the 25mg vial, is also being listed as a Limited Use benefit with the criteria as noted above.

4. When do the changes for Enbrel, Humira and Stelara become effective?

The changes will be effective with a future Formulary Update anticipated for September 2010. A subsequent notice will be provided with the effective date.

5. What is the LU authorization period?

The LU authorization period for Enbrel, Humira and Stelara is 1 year.

6. The current therapeutic notes speak to the dosing of these products. Do the Limited Use criteria include this language?

Yes, the Limited Use criteria include dosing for each product as follows:

a) Enbrel:

Approvals will only allow for standard dosing for Enbrel[®] (Etanercept): the recommended dose is 50mg subcutaneous twice weekly for 12 weeks followed by maintenance therapy at 25 -50mg subcutaneous once weekly. The Committee to Evaluate Drugs noted that this is the Manufacturer's recommended dosing regimen, as approved by Health Canada. If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended and the physician should consider switching to an alternative biologic agent.

b) Humira:

Approvals will only allow for standard dosing for Humira[®] (adalimumab): the recommended dose is an initial 80mg administered subcutaneously, followed by 40mg subcutaneously given every other week starting one week after the initial dose. The Committee to Evaluate Drugs noted that this is the Manufacturer's recommended dosing regimen, as approved by Health Canada. If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended and the physician should consider switching to an alternative biologic agent.

c) Stelara:

Approvals will only allow for standard dosing for Stelara[®] 45 mg to be administered at weeks 0, 4 and every 12 weeks thereafter. If the patient has not responded after 12 weeks of treatment, the physician should consider switching to an alternative biologic agent.

NEW PATIENTS

7. How does this affect patients with a new prescription for Enbrel, Humira or Stelara?

If a new patient meets the Limited Use criteria for the treatment of severe plaque psoriasis and the Limited Use code is provided, the claim can be submitted through the Health Network System (HNS).

Indications for use in patients who do not meet the LU criteria (i.e. psoriatic and rheumatoid arthritis, other dermatological conditions, Crohn's disease, ankylosing spondylitis, etc.) require a patient-specific funding request and these should continue to be submitted through the Exceptional Access Program (EAP) by fax at 416-327-7526 or 1-866-811-9908. EAP criteria for other indications can be found on the Ministry's website:

http://www.health.gov.on.ca/english/providers/program/drugs/pdf/frequently_requested_drugs.pdf

PATIENTS CURRENTLY ON ENBREL OR HUMIRA

8. How does this change affect patients currently receiving Enbrel or Humira through the General Benefit PINs?

Once the change to Limited Use becomes effective, the PINs currently being used for claims submitted for Enbrel and Humira for the treatment of severe plaque psoriasis will be removed from the Formulary. Enbrel will be listed according to the current DINs for both formats (02274728 for the pre-filled syringe and 02242903 for the 25mg vial) and Humira will be listed according to the DIN/PIN used for EAP requests (02258595 for the pre-filled syringe and 09857294 for the pre-filled pen)

The pharmacist is responsible for verifying that the Limited Use criteria are met for patients currently on biologic therapy. If the Limited Use criteria are met, the Limited Use Code must be submitted with any subsequent claims for these products.

If patients do not meet the Limited Use criteria, a patient-specific funding request is required and these should continue to be submitted through the EAP by fax at 416-327-7526 or 1-866-811-9908.

9. The Limited Use criteria necessitate that the claims for the first 6 months must be written by a dermatologist. Does this apply to patients that have already been on therapy for longer than 6 months?

No, patients who meet the Limited Use criteria and who started on therapy more than 6 months prior to the claim do not need to have their current prescriptions written by a dermatologist.

10. Will the HNS apply the 30-Day Prescription Program when a new LU claim is submitted?

Yes, the HNS will apply the 30 day supply limit to new Limited Use claims submitted even if a patient has received the therapy previously (due to the introduction of new DIN/PINs). However, the response code "OF" associated with this can be over-ridden for patients who have been on therapy for more than 30 days with the intervention code "NH".

11. How does this change affect patients currently receiving Enbrel or Humira through the Exceptional Access Program (EAP)?

Patients who have received approval for Enbrel or Humira are not affected by these changes. Renewals should continue to be submitted through EAP.

12. Where do I go for assistance on submitting claims?

Please contact the ODB Help Desk at 1-800-668-6641 if you require assistance with on-line claims submissions.