Effective
June 1, 2008

ADDITIONS
To The Alberta Health & Wellness
Drug Benefit List (AHWDBL)

Summary

Special Authorization Drug Products with Changes to Criteria

Special Authorization Drug Products with Changes to Criteria

Alberta Blue Cross has been advised by Alberta Health and Wellness that the criteria for coverage has been revised effective June 1, 2008, for the following special authorization products, Humira and Enbrel.

Please note: the criteria listed below are provided as an addition to the existing criteria as presented in the April 1, 2008 *Alberta Health and Wellness Drug Benefit List* for the following special authorization products. To view the full criteria please refer to the online Drug Benefit Publications at: http://www.health .alberta.ca/ahcip/ahcip_list.html

Ankylosing Spondylitis:

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'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.

For coverage, this drug must be initiated by a Specialist in Rheumatology.

- Initial coverage may be approved for 12 weeks as follows: An initial 40 mg dose, followed by additional 40 mg doses administered every two weeks for up to 12 weeks after the first dose.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients who are intolerant to adalimumab will be permitted to switch to etanercept.
- Patients who have not responded to an adequate trial of adalimumab will not be eligible for coverage of other anti-TNF agents.
- Patients are limited to receiving one biologic (i.e. anti-TNF or other monoclonal antibody agent) at a time regardless of the condition for which it is being prescribed.

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- Coverage will not be approved when another anti-TNF agent is intended for use in combination with adalimumab.

For continued coverage of this biologic agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed at 12 weeks by a Rheumatology Specialist after the initial twelve weeks of therapy with this biologic agent to determine response.
2) The Rheumatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

A patient who demonstrates response, as defined by the above criteria, will be eligible for maintenance coverage for 12 months.

The maximum amount of adalimumab approved for maintenance coverage will not exceed a total of twenty-six 40 mg doses per year.

In order to be considered for continued coverage after 12 months, the patient must be re-assessed by an RA Specialist and must be confirmed to be continuing to respond to therapy."

All requests (including renewal requests) for adalimumab for Ankylosing Spondylitis must be completed using the Enbrel/Humira for Ankylosing Spondylitis Special Authorization Request Form (ABC 31195).

Humira 40 mg/ 0.8 ml injection syringe

ADALIMUMAB
40 MG / SYR INJECTION SYRINGE

00002258595	HUMIRA	ABB	$	752.1197

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- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'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.

For coverage, this drug must be initiated by a Specialist in Rheumatology.

- Initial coverage may be approved for twelve weeks of 50 mg/week.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.

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- Patients who are intolerant to entanercept will be permitted to switch to adalimumab.
- Patients who have not responded to an adequate trial of etanercept will not be eligible for coverage of other anti-TNF agents.
- Patients are limited to receiving one biologic (i.e. anti-TNF or other monoclonal antibody agent) at a time regardless of the condition for which it is being prescribed.
- Coverage will not be approved when another anti-TNF agent is intended for use in combination with etanercept.

For continued coverage of this biologic agent beyond twelve weeks, the patient must meet the following criteria:
1) The patient must be assessed at twelve weeks by a Rheumatology Specialist after the initial twelve weeks of therapy with this biologic agent to determine response.
2) The Rheumatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

A patient who demonstrates response, as defined by the above criteria, will be eligible for maintenance coverage for 12 months.

The maximum amount of etanercept approved for maintenance coverage will not exceed 50 mg per week per year.

In order to be considered for continued coverage after 12 months, the patient must be re-assessed by an RA Specialist and must be confirmed to be continuing to respond to therapy."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Enbrel/Humira for Ankylosing Spondylitis Special Authorization Request Form (ABC 31195).

Enbrel 25mg/vial injection and Enbrel 50 mg/ml injection syringe

ETANERCEPT

25 MG/ VIAL INJECTION

00002242903	ENBREL	AMG	$	201.6745

50 MG/ SYR INJECTION SYRINGE

00002274728	ENBREL	AMG	$	403.3490