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PHARMACISTS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

New Exception Status Benefits

The following product has been reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as an exception status benefit, with the following criteria, effective June 1, 2016

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inflectra (infliximab)	100mg Pdr for Inj	02419475	DNP	E (SF)	HOS

Criteria

For infliximab-naïve patients whose infliximab therapy is initiated after June 1, 2016, Infectra will be the product approved for the following indications:

Ankylosing Spondylitis:

For the treatment of patients with moderate to severe ankylosing spondylitis (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.

Notes:

- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inflectra (infliximab)	100mg Pdr for Inj	02419475	DNP	E (SF)	HOS

Criteria

- 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")

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

- Initial coverage period 6 months, maximum dose 5mg/kg at 0, 2, and 6 weeks then every 6-8 weeks thereafter and not in combination with other anti-TNF agents.

Psoriasis:

For patients with severe, debilitating chronic plaque psoriasis (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; AND
- written request of a dermatologist or prescriber with a specialty in dermatology.

Continued coverage is dependent on evidence of improvement, specifically:

- ≥ 75% reduction in the Psoriasis Area and Severity Index (PASI) score; OR
- ≥ 50% reduction in PASI with a ≥ 5 point improvement in DLQI (Dermatology Life Quality Index); OR
- significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.

Concurrent use of biologics not approved.

Initial approval for a maximum of 12 weeks. Dosage restricted to infliximab 5mg/kg 0, 2 and 6 weeks then every 8 weeks.

Rheumatoid Arthritis:

- Refer to RA criteria included in this bulletin.

…New Exception Status Benefits continued on Page 6

Criteria Updates – Rheumatoid Arthritis

The Atlantic Common Drug Review (ACDR) reviewed the Rheumatoid Arthritis criteria for biologics and based on updated evidence, effective June 1, 2016, the revised criteria will apply to the following drugs:

- abatacept Inj
- adalimumab Pen and Inj
- certolizumab pegol SC Inj
- etanercept Inj
- golimumab Autoinjector and Syringe
- infliximab Pdr for Inj
- tocilizumab IV Inj and SC Inj

Criteria:

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), or use in combination with another DMARD, for a minimum of 12 weeks

  AND

- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 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 to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- 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.

Criteria Updates – Rheumatoid Arthritis Continued…

- Maximum Dosage Approved:
  - Abatacept Intravenous infusion: 500mg for patients <60 kg, 750mg for patients 60-100 kg and 1000mg for patients >100 kg, given at 0, 2, and 4 weeks then every 4 weeks thereafter. Subcutaneous injection: a single IV loading dose of up to 1,000mg may be given, followed by 125mg subcutaneous injection within a day, then once-weekly 125mg subcutaneous injections
  - Adalimumab: 40mg every two weeks with no dose escalation permitted
  - Certolizumab pegol: 400mg at weeks 0, 2 and 4 weeks, then 200mg every 2 weeks (or 400mg every 4 weeks) with no dose escalation permitted
  - Etanercept: 25mg twice a week or 50mg once a week with no dose escalation permitted
  - Golimumab: 50mg once a month with no dose escalation permitted
  - Infliximab (Remicade): 3mg/kg/dose at 0, 2 and 6 weeks, then every 8 weeks thereafter
  - Infliximab (Inflectra): 3mg/kg/dose at 0, 2 and 6 weeks, then every 8 weeks thereafter
  - Tocilizumab: 4mg/kg/dose once every 4 weeks followed by an increase to 8 mg/kg/dose based on clinical response

As per the Canadian Drug Expert Committee (CDEC) recommendation, tocilizumab IV will be listed to include the following criteria for the management of Polyarticular Juvenile Idiopathic Arthritis, effective June 1, 2016:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Actemra (tocilizumab)	80mg/4mL Inj	02350092	DNP	E (SF)	HLR
	200mg/10mL Inj	02350106	DNP	E (SF)	HLR
	400mg/20mL Inj	02350114	DNP	E (SF)	HLR
Criteria	• For the treatment of children (age 2-17) with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) who have had inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). Notes: • Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children. • Intravenous infusion: Approvals will be for 10mg/kg for patients <30kg or 8mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every four weeks. • Initial approval period: 16 weeks • Renewal Approval: 1 year. Confirmation of continued response is required.				

New Exception Status Benefits

The following product has been reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as an exception status benefit, with the following criteria, effective June 1, 2016.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zaxine (rifaximin)	550mg Tab	02410702	DNP	E (SF)	LUP
Criteria	For reducing the risk of overt hepatic encephalopathy (HE) recurrence if the following clinical criteria are met: • patients are unable to achieve adequate control of HE recurrence with lactulose alone • used in combination with a maximal tolerated dose of lactulose				

New Interchangeable Categories

A Maximum Reimbursable Price (MRP) or Pharmacare Reimbursement Price (PRP) has been established for the following products. Benefit status is effective May 20, 2016.

PRODUCT	DIN/PIN	PRESCRIBER	BENEFIT STATUS MAY 20, 2016	MRP/PRP* JUNE 10, 2016	MFR
duloxetine 30mg cap					
Apo-Duloxetine 30mg Cap	02440423	DNP	E (SF)	0.4814	APX
Auro-Duloxetine 30mg Cap	02436647	DNP	E (SF)	0.4814	ARO
Duloxetine DR 30mg Cap	02437082	DNP	E (SF)	0.4814	TEV
Jamp-Duloxetine 30mg Cap	02451913	DNP	E (SF)	0.4814	JPC
Mar-Duloxetine 30mg Cap	02446081	DNP	E (SF)	0.4814	MAR
MINT-Duloxetine 30mg Cap	02438984	DNP	E (SF)	0.4814	MNT
pms-Duloxetine 30mg Cap	02429446	DNP	E (SF)	0.4814	PMS
Ran-Duloxetine 30mg Cap	02438259	DNP	E (SF)	0.4814	RAN
Sandoz Duloxetine 30mg Cap	02439948	DNP	E (SF)	0.4814	SDZ
Cymbalta 30mg Cap	02301482	DNP	E (SF)	0.4814	LIL
duloxetine 60mg cap					
Apo-Duloxetine 60mg Cap	02440431	DNP	E (SF)	0.9769	APX
Auro-Duloxetine 60mg Cap	02436655	DNP	E (SF)	0.9769	ARO
Duloxetine DR 60mg Cap	02437090	DNP	E (SF)	0.9769	TEV
Jamp-Duloxetine 60mg Cap	02451921	DNP	E (SF)	0.9769	JPC
Mar-Duloxetine 60mg Cap	02446103	DNP	E (SF)	0.9769	MAR
MINT-Duloxetine 60mg Cap	02438992	DNP	E (SF)	0.9769	MNT
pms-Duloxetine 60mg Cap	02429454	DNP	E (SF)	0.9769	PMS
Ran-Duloxetine 60mg Cap	02438267	DNP	E (SF)	0.9769	RAN
Sandoz Duloxetine 60mg Cap	02439956	DNP	E (SF)	0.9769	SDZ
Cymbalta 60mg Cap	02301490	DNP	E (SF)	0.9769	LIL

Change in Benefit Status

The following categories will be listed as full benefits, effective May 20, 2016.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Indapamide	1.25mg Tab	Various	DNP	SF	VAR
Indapamide	2.5mg Tab	Various	DNP	SF	VAR

Change in Category Pricing

The following category will change from MLP to MRP, effective June 1, 2016.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Citalopram	10mg Tab	Various	DNP	SFC	VAR

Palliative Care Drug Program Updates

As you may know, the Nova Scotia Palliative Care Drug Program is available for those who need assistance covering medications used in palliative care. This program ensures that the cost of medications does not create a financial barrier for those who wish to receive end-of-life care at home.

Over the past year the Department of Health and Wellness has been collaborating with Palliative Care teams and specialists to provide supports and education regarding the best use of the program. The goal of working collaboratively is to support the most effective use of this program.

Part of this work has resulted in additional documents and tools that may be helpful to you in your practice. This additional information can be found on our website at:

http://novascotia.ca/dhw/pharmacare/palliative-drug-program.asp

The information includes, but is not limited to a Formulary, a brief comparison chart reviewing the various Pharmacare Programs, and Frequently Asked Questions.

Claims are to continue to be submitted online as per other programs, using the patient identification number and a carrier ID of NS. Further information is available in the Pharmacists' Guide available at:

http://novascotia.ca/dhw/pharmacare/pharmacists-guide.asp