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PHARMACISTS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

Extension of Coverage for Exception Status Medications

To support Nova Scotia residents and healthcare providers during the COVID-19 pandemic and to ensure Pharmacare beneficiaries have continued access to specific medications, the following changes are effective immediately:

- Approvals for coverage of exception status drugs that will be expiring before July 1, 2020 will be extended for an additional three months. For example, requests expiring May 23rd will now expire August 23rd. In addition, those that expired in February and have not already been renewed, have been extended to July 1, 2020.
- Usual quantity limits for biologics will continue to apply as per specific coverage criteria limits.
- This change applies to renewals for coverage. New requests for coverage should continue to be submitted as per usual processes.

New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ocrevus (ocrelizumab)	300mg/10mL Vial	02467224	DNP	E (SF)	HLR

Criteria

Primary Progressive Multiple Sclerosis

- For the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) who meet all of the following criteria:
    - Confirmed diagnosis based on McDonald criteria
    - Recent Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5
    - Recent Functional Systems Scale (FSS) score of at least 2 for the pyramidal functions component due to lower extremity findings
    - Disease duration of 10 years for those with an EDSS of less than or equal to 5 or disease duration less than 15 years for those with an EDSS greater than 5
    - Diagnostic imaging features characteristic of inflammatory activity
    - Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Relapsing Remitting Multiple Sclerosis

- For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
    - Confirmed diagnosis based on McDonald criteria
    - Experienced one or more disabling relapses or new MRI activity in the last two years
    - Are fully ambulatory without aids (i.e., must provide a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 5.5)
    - Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 6.

Claim Notes:

- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Claims for Ocrevus 300mg/10mL Vial that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN:
    - 00904527

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fulphila (pegfilgrastim)	6mg/0.6mL (10mg/mL) PF Sol for Inj	02484153	DNP	E (SFC)	BGP
Lapelga (pegfilgrastim)	6mg Pre-filled Syringe	02474565	DNP	E (SFC)	APX
Criteria	• For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who: ○ are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; or ○ have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or ○ have had a dose reduction, or treatment delay greater than one week due to neutropenia. **Clinical Note:** • Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.				

Criteria Update

The following criteria has been updated effective **immediately:**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tafinlar (dabrafenib)	50mg Cap	02409607	DNP	E (SFC)	NVR
	75mg Cap	02409615	DNP	E (SFC)	NVR
Mekinist (trametinib)	0.5mg Tab	02409623	DNP	E (SFC)	NVR
	2mg Tab	02409658	DNP	E (SFC)	NVR
Criteria	• Dabrafenib-trametinib combination therapy as a first-line BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms. • In the event that a patient is initiated on dabrafenib-trametinib combination therapy and has to discontinue one agent due to toxicity, dabrafenib or trametinib monotherapy as a first-line BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1, will be funded, should that be the chosen treatment option. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms. For clarity, initiation of treatment with dabrafenib or trametinib monotherapy will not be funded. • For the adjuvant treatment of patients with stage IIIA (limited to lymph node metastases of > 1 mm) to stage IIID (8th edition of American Joint Committee on Cancer [AJCC]				

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tafinlar	50mg Cap	02409607	DNP	E (SFC)	NVR
(dabrafenib)	75mg Cap	02409615	DNP	E (SFC)	NVR
Mekinist	0.5mg Tab	02409623	DNP	E (SFC)	NVR
(trametinib)	2mg Tab	02409658	DNP	E (SFC)	NVR

Criteria

staging system) BRAF-mutated (all BRAF V600 mutations) cutaneous melanoma. Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed.

Clinical Notes:

- Patients should have a good performance status.
- Treatment with dabrafenib plus trametinib should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.
- Patients are eligible to receive 12 months of adjuvant treatment with immunotherapy or BRAF targeted therapy. Patients who are unable to tolerate initial adjuvant therapy, within the first 3 months of treatment, may switch to alternate funded treatment, provided criteria are met.
- Patients with mucosal or ocular melanoma are not eligible for treatment with dabrafenib/trametinib.
- Patients who relapse during, or at any time after adjuvant dabrafenib/trametinib therapy, are eligible for treatment with combination immunotherapy (i.e. nivolumab with ipilimumab) in the metastatic setting. Patients who are not candidates for combination immunotherapy are eligible for single agent nivolumab or pembrolizumab immunotherapy in the metastatic setting.
- Re-treatment with BRAF targeted therapy is funded if the treatment-free interval is ≥ 6 months from the completion of adjuvant BRAF therapy.