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PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erleada (apalutamide)	60mg Tab	02478374	DNP	E (SFC)	JAN

Criteria

- In combination with androgen deprivation therapy (ADT) for the treatment of patients with castration-resistant prostate cancer (CRPC) who have no detectable distant metastasis (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases[1].
- Patients should have a good performance status and no risk factors for seizures. Treatment should continue until unacceptable toxicity or radiographic disease progression.

Clinical Notes:

- Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA > 2 ng/mL.
- Castrate levels of testosterone must be maintained.
- Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the common iliac vessels are eligible for apalutamide.
- Apalutamide will not be funded for patients who experience disease progression on enzalutamide.
- Patients receiving apalutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on apalutamide.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erleada (apalutamide)	60mg Tab	02478374	DNP	E (SFC)	JAN
Criteria	• Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued apalutamide in the non-metastatic setting due to intolerance without disease progression. 1. High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Radicava (edaravone)	30mg/100mL IV Inj	02475472	DNP	E (SF)	MBT
Criteria	For the treatment of amyotrophic lateral sclerosis (ALS), if the following criteria are met: **Initiation Criteria** • Patient with a diagnosis of probable ALS or definite ALS; AND • Patient who meets all of the following: o has scores of at least two points on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R) o has a forced vital capacity greater than or equal to 80% of predicted o has had ALS symptoms for two years or less o patient is not currently requiring permanent non-invasive or invasive ventilation. **Renewal Criteria** • Reimbursement of treatment should be discontinued in patients who meet any one of the following criteria: o patient becomes non-ambulatory (ALSFRS-R score ≤ 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRS-R score < 1 for item 5a or 5b); OR o patient requires permanent non-invasive or invasive ventilation. **Claim Notes:** • Patient must be under the care of a specialist with experience in the diagnosis and management of ALS. • Claims for Radicava 30mg/100mL IV Injection 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: o 00904538				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Afinitor	2.5mg Tab	02369257	DNP	E (SFC)	NVR
(everolimus)	5mg Tab	02339501	DNP	E (SFC)	NVR
	10mg Tab	02339528	DNP	E (SFC)	NVR
Criteria	• For the treatment of patients with advanced or metastatic renal cell carcinoma following disease progression on tyrosine kinase inhibitor therapy. **Clinical Notes**: • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Requests for everolimus will not be considered for patients who experience disease progression on axitinib, cabozantinib or nivolumab monotherapy.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fibristal	5mg Tab	02408163	DNP	E (F)	ALL
(ulipristal acetate)					
Criteria	• For the treatment of adult women of reproductive age with moderate to severe uterine fibroids as either: o Pre-operative treatment in patients who are eligible for surgery; OR o Intermittent treatment in patients who are not eligible for surgery. **Clinical Note:** • Each course of treatment is three months in duration. **Claim Notes:** • The maximum quantity reimbursed is limited to four courses of treatment. • The patient must be under the care of a physician experienced in the management of gynecological conditions such as uterine fibroids.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inlyta	1mg Tab	02389630	DNP	E (SFC)	PFI
(axitinib)	5mg Tab	02389649	DNP	E (SFC)	PFI
Criteria	• As second-line therapy for the treatment of patients with advanced or metastatic renal cell carcinoma (RCC), after failure of first-line tyrosine kinase inhibitor therapy. **OR** • As third-line therapy for the treatment of patients with advanced or metastatic renal cell carcinoma (RCC), after failure of first-line immunotherapy, and second-line tyrosine kinase inhibitor therapy. **Clinical Notes:** • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Sequential use of axitinib and everolimus is not permitted except in the case of intolerability or contraindication. • For patients treated with nivolumab + ipilimumab first-line and VEGF TKI (sunitinib or pazopanib) second line, either cabozantanib **or** axitinib may be used as third-line therapy. • Sequential use of cabozantanib and axitinib (as a single agent) is not funded except in the case of intolerance or contraindication. • Both clear cell and non-clear cell histology are eligible for treatment.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nexavar	200mg Tab	02284227	DNP	E (SFC)	BAY
(sorafenib)					
Criteria	• For the treatment of patients with advanced or metastatic renal cell carcinoma when used as a second-line therapy following disease progression on cytokine therapy. **Clinical Notes:** • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sutent (sunitinib)	12.5mg Cap 25mg Cap 50mg Cap	02280795 02280809 02280817	DNP DNP DNP	E (SFC) E (SFC) E (SFC)	PFI PFI PFI
Criteria	• For patients with advanced or metastatic renal cell carcinoma as either first-line therapy, or second-line therapy after failure of first-line immunotherapy. **Clinical Notes:** • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Sunitinib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib, or pazopanib) as sequential therapy. • In the event of significant toxicity, a switch to another tyrosine kinase inhibitor (i.e., sorafenib or pazopanib) may be allowed. • Both clear cell and non-clear cell histology are eligible for treatment.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Votrient (pazopanib)	200mg Tab	02352303	DNP	E (SFC)	NVR
Criteria	• For patients with advanced or metastatic renal cell carcinoma as either first-line therapy, or second-line therapy after failure of first-line immunotherapy. **Clinical Notes:** • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Pazopanib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib, or sunitinib) as sequential therapy. • In the event of significant toxicity, a switch to another tyrosine kinase inhibitor (i.e., sorafenib or sunitinib) may be allowed. • Both clear cell and non-clear cell histology are eligible for treatment.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Venclexta (venetoclax)	10mg Tab	02458039	DNP	E (SFC)	ABV
	50mg Tab	02458047	DNP	E (SFC)	ABV
	100mg Tab	02458055	DNP	E (SFC)	ABV
	Starter Pack	02458063	DNP	E (SFC)	ABV
Criteria	• In **combination** with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy, irrespective of their 17p deletion status. Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of two years, whichever comes first. **Clinical Notes**: • Patients who were previously treated with and responded to an anti-CD20 therapy (rituximab or obinutuzumab) will be eligible for treatment with the combination of venetoclax plus rituximab if they had a progression-free interval of 12 months or longer. • Patients currently receiving and responding to venetoclax monotherapy, and who have not achieved an adequate response are eligible to have rituximab added to venetoclax. Note: Venetoclax therapy is funded to a maximum of two years from the time rituximab is added. • Patients may be retreated with venetoclax plus rituximab if they responded to and completed two years of therapy with at least 12 months of progression-free interval. • Patients will be eligible for treatment with either ibrutinib, or idelalisib with rituximab following progression on venetoclax with rituximab if they have not received before and otherwise meet eligibility criteria.				

New Diabetic Product

The following product is a new listing to the Nova Scotia Formulary, effective immediately. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	DIN/PIN	PRESCRIBER	BENEFIT STATUS	MFR
Droplet Micron Pen Needle 34G x 3.5mm	97799086	DNP	SFD	SFA

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	ALL - Allergan Inc.
P - Pharmacist	- Family Pharmacare	BAY - Bayer Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	JAN - Janssen-Ortho Inc.
O - Optometrist	D - Diabetes Assistance Program	MBT - Mitsubishi Tanabe Pharma Canada
	E - Exception status applies	NVR - Novartis Pharmaceuticals Canada Inc.
		PFI - Pfizer Canada Inc.
		SFA - Strefa