Health and Community Services

APALUTAMIDE (ERLEADA) 60 MG TABLET

Non-metastatic Castration-resistant Prostate Cancer
In combination with androgen deprivation therapy (ADT) for the treatment of patients with castration-resistant prostate cancer who meet all of the following criteria:

- No detectable distant metastases by either CT, MRI or technetium-99m bone scan
- Prostate-specific antigen (PSA) doubling time of less than or equal to 10 months during continuous ADT (i.e., high risk of developing metastases)

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression.

Clinical Notes:

1. Castration-resistance must be demonstrated during continuous ADT and is defined as a minimum of three rises in PSA, measured at least one week apart, with the last PSA greater than 2 mcg/L.
2. Castrate levels of testosterone must be maintained throughout treatment with apalutamide.
3. Patients must have a good performance status and no risk factors for seizures.
4. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Requests for apalutamide will not be considered for patients who experience disease progression on enzalutamide.
- Initial approval period: 1 year.
- Renewal approval period : 1 year

Metastatic Castration-sensitive Prostate Cancer
In combination with androgen deprivation therapy (ADT) for the treatment of patients with
metastatic castration-sensitive prostate cancer (mCSPC).

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must be castration sensitive (i.e., no prior ADT in the metastatic setting or within six months of beginning ADT).
2. Patients must have a good performance status and no risk factors for seizures.

3. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Requests for apalutamide will not be considered for patients who experience disease progression on enzalutamide.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

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