DAROLUTAMIDE (NUBEQA) 300 MG TABLET

In combination with androgen-deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) 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 3 PSA rises at least one week apart, with the last PSA > 2 ng/mL.
2. Castrate levels of testosterone must be maintained.
3. Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the aortic bifurcation are eligible for darolutamide.
4. Patients should have good performance status.
5. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Darolutamide will not be funded for patients who experience disease progression on apalutamide or enzalutamide.
- Patients receiving darolutamide 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 darolutamide.
- Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued darolutamide in the non-metastatic setting due to intolerance without disease progression.
- Initial approval period: 1 year
- Renewal approval period : 1 year