PRIOR AUTHORIZATION POLICY

POLICY:  Oncology – Erleada (apalutamide tablets – Janssen Pharmaceuticals)

TAC APPROVAL DATE:  02/27/2019

OVERVIEW
Erleada is indicated for the treatment of patients with non-metastatic, castration-resistant prostate cancer (NM-CRPC).\(^1\) Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or the patient should have had a bilateral orchiectomy. Erleada is an androgen receptor inhibitor that binds directly to the ligand-binding domain of the androgen receptor. Erleada administration caused decreased tumor cell proliferation and increased apoptosis leading to decreased tumor volume in animal models of prostate cancer.

GUIDELINES
According to the National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer, (version 4.2018 – August 15, 2018) for NM-CRPC, androgen deprivation therapy (ADT) is continued to maintain castrate serum levels of testosterone (< 50 ng/dL).\(^2\) Observation is noted as an option especially if the prostate specific antigen (PSA) doubling time (PSADT) is ≥ 10 months. Erleada and Xtandi\(^\text{®}\) (enzalutamide capsules) are category 1 recommended options especially if the PSADT is ≤ 10 months. Other secondary hormone therapy is recommended if PSADT is ≤ 10 months (category 2A): for non-metastatic (M0) CRPC, the options are nilutamide, flutamide, bicalutamide, ketoconazole, corticosteroids.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Erleada. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Erleada is recommended in those who meet the following criteria:

FDA-Approved Indications

1.  Prostate Cancer – Non-Metastatic, Castration-Resistant.  Approve Erleada for 3 years.
CONDITIONS NOT RECOMMENDED FOR APPROVAL

Erleada has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES


HISTORY

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<th>Summary of Changes</th>
<th>TAC Approval Date</th>
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<tr>
<td>New Policy</td>
<td>New criteria</td>
<td>02/16/2018</td>
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<tr>
<td>Annual revision</td>
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For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx; TAC – Therapeutic Assessment Committee.