CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL POLICY

Erdafitinib (Balversa®)

Version: 1.0

EFFECTIVE DATE: 12/1/2024

NantHealth® | Eviti®

Please note the following:

Erdafitinib (Balversa®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Erdafitinib (Balversa): Discussion

Erdafitinib is a novel pan-FGFR inhibitor (pan - Fibroblast growth factor) which binds to the FGFR2 and FGFR3 receptors inhibiting FGF activity, resulting in cell death.[1] FGF signaling via FGF receptors (FGFR1-4) directs fetal development and contributes to tissue and whole-body homeostasis, but can also promote tumorigenesis.[2]

Erdafitinib can cause central serous retinopathy and retinal pigment epithelial detachment. An increase in phosphate levels is one of the pharmacodynamic effects of erdafitinib which causes hyperphosphatemia. Embryo-fetal toxicity is another potential risk with the use of erdafitinib.

Erdafitinib is approved by the Food and Drug Administration (FDA) for urothelial carcinoma.[3]

The National Comprehensive Cancer Network (NCCN) endorses erdafitinib in the following cancer type: bladder.[4]

Erdafitinib: Definitions

- **National Comprehensive Cancer Network (NCCN)** - An alliance of more than 30 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Food and Drug Administration (FDA)** - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

Erdafitinib: Policy

Note: Coverage of erdafitinib will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

Erdafitinib will be considered for coverage when the following criteria are met:

Bladder Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Used as second-line systemic therapy post-platinum or other chemotherapy or post-checkpoint inhibitor as a single agent for patients with susceptible FGFR3 genetic alterations and chemotherapy naive for one of the following:
   a) Stage II (CT2, N0) disease or stage IIIA (CT3, N0; CT4A, N0; CT1-T4A, N1) disease if the tumor is present following the reassessment of the tumor status 2-3 months after the primary treatment with concurrent bladder preserving chemoradiotherapy and maximal transurethral resection of bladder tumor (TURBT)
   b) Stage IIIB (CT1-T4A, N2,3) disease following the partial response or progression after primary treatment with downstaging systemic therapy or concurrent chemoradiotherapy
   c) Stage IVA (any T, any N, M1A) disease if stable or progression following the reassessment of the tumor status after primary treatment with first-line systemic therapy
   d) Metastatic stage IVB (any T, any N, M1b) disease
   e) Muscle invasive local recurrence or persistent disease in a preserved bladder treated with curative intent
   f) Metastatic or local recurrence post cystectomy treated with curative intent; OR
4. Second-line systemic therapy (if a first-line therapy containing both platinum chemotherapy and an immune checkpoint inhibitor was used, including maintenance checkpoint inhibitor), or as subsequent-line systemic therapy (patients should have already received platinum and a checkpoint inhibitor, if eligible) as a single agent for patients with susceptible FGFR3 genetic alterations for one of the following:
   a) Stage II (cT2, N0) disease or stage IIIA (cT3, N0; cT4a, N0; cT1-T4a, N1) disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with concurrent bladder preserving chemoradiotherapy and maximal TURBT
   b) Stage IIIB (cT1-T4a, N2,3) disease following partial response or progression after primary treatment with downstaging systemic therapy or concurrent chemoradiotherapy
   c) Stage IVA (cT4b, any N, M0) disease if tumor is present following reassessment of tumor status after primary treatment with first-line systemic therapy or concurrent chemoradiotherapy
   d) Stage IVA (any T, any N, M1a) disease if stable disease or progression following reassessment of tumor status after primary treatment with first-line systemic therapy
   e) Metastatic stage IVB (any T, any N, M1b) disease
   f) Muscle invasive local recurrence or persistent disease in a preserved bladder treated with curative intent
   g) Metastatic or local recurrence post cystectomy treated with curative intent.

Upper Genitourinary (GU) Tract Tumors/Urothelial Carcinoma of the Prostate

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Therapy for metastatic disease with susceptible FGFR3 alterations as a single agent for the following:
   a) Second-line systemic therapy post-platinum or other chemotherapy
   b) Second-line systemic therapy post-checkpoint inhibitor and chemotherapy naive
   c) Second-line systemic therapy if a first-line therapy containing both platinum chemotherapy and an immune checkpoint inhibitor was used, including maintenance checkpoint inhibitor
   d) Subsequent-line systemic therapy (patients should have already received a platinum and a checkpoint inhibitor, if eligible).

Primary Carcinoma of the Urethra

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Therapy for recurrent or metastatic disease as a single agent with susceptible FGFR3 genetic alterations as the following:
   a) Second-line systemic therapy post-platinum or other chemotherapy
   b) Second-line systemic therapy post-checkpoint inhibitor and chemotherapy naive
   c) Second-line systemic therapy if a first-line therapy containing both platinum chemotherapy and an immune checkpoint inhibitor was used, including a maintenance checkpoint inhibitor
   d) Subsequent-line systemic therapy (patients should have already received a platinum and a checkpoint inhibitor, if eligible).[3,4]

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Erdafitinib: References

1. Roubal et al. Erdafitinib: A novel therapy for FGFR-mutated urothelial cancer. https://pubmed.ncbi.nlm.nih.gov/32073123/. Accessed November 26, 2024.
2. Katoh et al. FGFR-targeted therapeutics: clinical activity, mechanisms of resistance and new directions. https://pubmed.ncbi.nlm.nih.gov/38424198/. Accessed November 26, 2024.
3. Erdafitinib Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/212018s010lbl.pdf. Accessed November 26, 2024.

4. National Comprehensive Cancer Network. Bladder Cancer. https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed November 26, 2024.

Erdafitinib: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

Code	Description
C67.5	Malignant neoplasm of bladder neck
C67.9	Malignant neoplasm of bladder
C68.0	Malignant neoplasm of urethra
C68.9	Malignant neoplasm of urinary organ
J8999	Erdafitinib

Erdafitinib: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	12/1/2024
2	Policy Review Dates:	
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee:	12/21/2024
6	Revision Changes:	