

Erdafitinib (BALVERSA)

Criteria for Use

March 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or [PBM INTRAnet](#) for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive Erdafitinib.

- Serum phosphate above the upper limit of normal
- Symptomatic CNS metastases
- Any corneal or retinal abnormality identified by ophthalmologic exam
- Unmanageable CYP2C9 or CYP3A4 drug interaction
- Unmanageable CYP3A4, OAT2, or P-glycoprotein substrate drug interaction
- Pregnancy (i.e. known pregnancy or positive pregnancy test)
- Breastfeeding

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.*

- Care is provided by a VA/VA Community Care oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- Goals of care and role of Palliative Care consult have been discussed and documented
- Baseline ophthalmologic exam, including Optical Coherence Tomograph (OCT) where available
- Patients of child-bearing potential and patients with partners of child-bearing potential: counseling provided on contraception and risks vs. benefits of treatment. Use effective contraception during therapy and for 1 month after the last dose.

*For known Poor Metabolizer genotype (CYP2C9*3/*3), monitor for increased risk of adverse events

Additional Inclusion Criteria

The answer to ALL of the following must be fulfilled in order to meet criteria:

- Locally advanced (unresectable) or metastatic urothelial carcinoma
- FGFR3 alteration based on companion diagnostic or next generation sequencing
- Progressed during or following at least 1 prior line of systemic therapy¹

¹Not recommended if patient is eligible for or has not received prior PD-1 or PD-L1 inhibitor therapy

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Updated version may be found at [PBM INTERnet](#) or [PBM INTRAnet](#)