Reference number(s)
5591-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☑
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Renal Cell Carcinoma (RCC)

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), and Value Formulary Chart (VFC).

Plan Design Summary

This program applies to the renal cell carcinoma products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with Fotivda for the first time. This program applies to all members requesting treatment with Nexavar, Sutent or Votrient.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Renal Cell Carcinoma (RCC) Therapies

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Cabometyx (cabozantinib) • Inlyta (axitinib) • Lenvima (lenvatinib) • pazopanib (generic) • sorafenib (generic) • sunitinib (generic)
Target	• Fotivda (tivozanib) • Nexavar (sorafenib) • Sutent (sunitinib) • Votrient (pazopanib)

Exception Criteria

This program applies to members requesting treatment for renal cell carcinoma.

- Coverage for Fotivda is provided when any of the following criteria are met:
  - Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
  - Member has a documented inadequate response or intolerable adverse event with at least 3 of the preferred products: a) Cabometyx, b) Inlyta, c) Lenvima, d) pazopanib, and e) sunitinib.
- Coverage for Nexavar is provided when both of the following criteria are met:
  - Member has a documented intolerable adverse event with sorafenib, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - Member has a documented inadequate response or intolerable adverse event with at least 3 of the preferred products: a) Cabometyx, b) Inlyta, c) Lenvima, d) pazopanib, and e) sunitinib.
- Coverage for Sutent is provided when both of the following criteria are met:
  - Member has a documented intolerable adverse event with sunitinib, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - Member meets either of the following:
    - Member has a documented inadequate response or intolerable adverse event with at least 3 of the preferred products: a) Cabometyx, b) Inlyta, c) Lenvima, and d) pazopanib.
    - Sutent is being requested for the adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy.
- Coverage for Votrient is provided when both of the following criteria are met:
  - Member has a documented intolerable adverse event with pazopanib, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - Member meets either of the following:

- Member has a documented inadequate response or intolerable adverse event with at least 3 of the preferred products: a) Cabometyx, b) Inlyta, c) Lenvima, and d) sunitinib.
- Member has von-Hippel Lindau (VHL) associated renal cell carcinoma (RCC).

References

1. Cabometyx [package insert]. Alameda, CA: Exelixis, Inc.; September 2023.
2. Fotivda [package insert]. Boston, MA: AVEO Pharmaceuticals, Inc.; August 2024.
3. Inlyta [package insert]. New York, NY: Pfizer Labs; July 2024.
4. Lenvima [package insert]. Nutley, NJ: Eisai Inc; June 2024.
5. Nexavar [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; August 2023.
6. Pazopanib [package insert]. Weston, FL: Apotex Corp.; February 2024.
7. Sorafenib [package insert]. Parsippany, NJ: Teva Pharmaceuticals; July 2022.
8. Sunitinib [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; September 2021.
9. Sutent [package insert]. New York, NY: Pfizer Labs; August 2021.
10. Votrient [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.