Axitinib (Inlyta®)

EOCCO POLICY

Policy Type: NF/SP Pharmacy Coverage Policy: EOCCO007

Description

Axitinib (Inlyta) is an orally administered tyrosine kinase inhibitor, including vascular endothelial growth factor receptors (VEGFR) that are responsible for tumor growth, angiogenesis, and disease progression.

Length of Authorization

- Initial: Three months
- Renewal: Six months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
axitinib (Inlyta)	1 mg tablets	Advance renal cell carcinoma	180 tablets/30 days	171511
	5 mg tablets		60 tablets/30 days	171512

Initial Evaluation

I. Axitinib (Inlyta) may be considered medically necessary when the following criteria below are met:
   A. Axitinib (Inlyta) is prescribed by, or in consultation with, an oncologist or urologist; **AND**
   B. A diagnosis of **Advanced Renal Cell Carcinoma (Relapsed or Stage IV)** when the following are met**:**
      1. Axitinib (Inlyta) will be used as <u>monotherapy</u>; **AND**
      2. Prior treatment with one of the following has been ineffective or not tolerated, unless ALL are contraindicated.
         i. sunitinib (Sutent)
         ii. temsirolimus (Torisel)
         iii. bevacizumab (Avastin)
         iv. pazopanib (Votrient)
         v. sorafenib (Nexavar)
         vi. everolimus (Afinitor); **OR**
      3. Axitinib (Inlyta) will be used in <u>combination</u> with pembrolizumab (Keytruda) as first-line therapy; **OR**
      4. Axitinib (Inlyta) will be used in <u>combination</u> with avelumab (Bavencio) as first-line therapy

II. Axitinib (Inlyta) is considered investigational when used for all other conditions, including but not limited to:
   A. Non-metastatic Stage I-III Renal Cell Carcinoma

Renewal Evaluation

I. Tumor response is documented with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
II. The member has an absence of unacceptable toxicity from the medication

Supporting Evidence

I. Axitinib (Inlyta) is indicated for advance renal cell carcinoma (RCC) after failure of one prior systemic therapy; or as first-line therapy when used in combination with pembrolizumab (Keytuda); or as first-line therapy when used in combination with avelumab (Bavencio).
II. The FDA approval of axitinib (Inlyta) in the setting of advanced RCC after failure of one prior systemic therapy was based on the results of a phase 3 trial (AXIS). In the AXIS trial, the primary end point was progression free survival in the intention-to-treat population. The median PFS was 6·7 months with axitinib compared to 4·7 months with sorafenib (hazard ratio 0·665; 95% CI 0·544-0·812; one-sided p<0·0001).
    - Note: Sunitinib (Sutent) is considered the first systemic agent to use for adjuvant treatment for all stages of RCC after primary treatment (surgical).
III. The FDA approval of pembrolizumab (Keytruda) in combination with axitinib (Inlyta) was based on the results of KEYNOTE-426, an open-label, phase 3 trial. In the KEYNOTE-426 trial, the primary end points were overall survival and progression-free survival in the intention-to-treat population. Statistical significance as achieved after a median follow-up of 12.8 months, the estimated percentage of untreated advanced RCC patients who were alive at 12 months was 89.9% in the pembrolizumab-axitinib group compared to 78.3% in the sunitinib group.
    - Note: Sunitinib (Sutent) is considered the first systemic agent to use for adjuvant treatment for all stages of RCC after primary treatment (surgical).
IV. The FDA approval of avelumab (Bavencio) in combination with axitinib (Inlyta) was based on positive results from the Phase III JAVELIN Renal 101 study, involving previously untreated advanced RCC patients. In the JAVELIN Renal 101 study, the median progression-free survival was 13.8 months with avelumab plus axitinib, as compared with 7.2 months with sunitinib.
    - Note: Sunitinib (Sutent) is considered the first systemic agent to use for adjuvant treatment for all stages of RCC after primary treatment (surgical).

Investigational or Not Medically Necessary Uses

I. Non-metastatic Stage I-III Renal Cell Carcinoma
   A. Axitinib (Inlyta) has not been studied in non-metastatic, non-advanced (stage I-III) renal cell carcinoma.

References

1. Inlyta [Prescribing Information]. New York, NY: Pfizer, Inc. August 2018.
2. Keytruda [Prescribing Information]. White House Station, NJ: MERCK & CO, Inc. April 2019.
3. Bavencio [Prescribing Information]. Rockland, MA: EMD Serono, Inc. May 2019.
4. Rini BI, Escudier B, Tomczak P, et al. Comparative effectiveness of axitinib versus sorafenib in advanced renal cell carcinoma (AXIS): a randomised phase 3 trial. Lancet. 2011 Dec 3;378(9807):1931-9. Doi: 10.1016/S0140-6736(11)61613-9.
5. Motzer R, Penkov K, Haanen J, et al. Avelumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma. N Engl J Med. 2019 Mar 380:1103-1115. Doi:10.1056/NEMJMoa1816047.
6. Rini B.I, Plimack E.R, Stus V., et al. Pembrolizumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma. N Engl J Med. 2019 Feb 380:1116-1127. Doi:10.1056/NEMJMoa1816714.

Policy Implementation/Update:

Date Created	July 2012
Date Effective	April 2016
Last Updated	June 2019
Last Reviewed	03/2016, 06/2019

Action and Summary of Changes	Date
Transitioned criteria to policy. In this transition, the following updates were made: added new indication for advance renal cell carcinoma to use axitinib (Inlyta) in combination with pembrolizumab (Keytruda) or avelumab (Bavencion) as first-line therapy.	06/2019