Drug Policy:
Cosela™ (trilaciclib)

I. PURPOSE

To define and describe the accepted indications for Cosela (trilaciclib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR

2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND

5. When available, generic alternatives are preferred over brand-name drugs.

B. Extensive Stage Small Cell Lung Cancer

1. Cosela (trilaciclib) is not recommended for use per NCH Policy.

   Rationale: Based on a review of the 3 studies conducted on this drug, we noted that:

   a. The incidence of febrile neutropenia was not used as an efficacy end-point in any of the trials.
   b. G-CSF use was allowed starting cycle 2 for all 3 trials. A significant proportion of patients received G-CSF in both the placebo and Cosela groups. The use of IV antibiotics was 22% in the Cosela group vs 28% in the placebo group-a non-significant difference in the trial using Cosela with topotecan.
   c. There is no Level 1 evidence (randomized trial and/or meta-analysis) to support that Cosela + G-CSF therapy significantly decreases the risk of febrile neutropenia compared to G-CSF therapy alone.
   d. With regards to anemia prevention, the rate of ESA use for anemia of chemotherapy was 3% in the Cosela group vs 5% in the placebo group-a non-significant difference-in the trial using a 3-drug regimen.
   e. With regards to platelet transfusions: 8 patients received platelet transfusions in the Cosela group compared to 9 patients in the placebo group-a non-significant difference-in the trial using topotecan.
   f. Based on our review, the use of Cosela does not offer significant clinical benefits in terms of decreasing myelosuppression, over and above the use of G-CSF, and other supportive care (ESAs, platelet transfusions etc.).
   g. None of these studies showed an improvement in Progression-Free Survival (PFS) or Overall Survival (OS).

III. EXCLUSION CRITERIA

A. AGENT NOT RECOMMENDED PER POLICY

IV. APPROVAL AUTHORITY

A. Review – Utilization Management Department
   B. Final Approval – Utilization Management Committee

V. ATTACHMENTS

A. None

VI. REFERENCES

