POLICY NUMBER UM ONC_1201	SUBJECT Yervoy™ (ipilimumab)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 01/04/12, 10/16/13, 10/14/15, 04/13/16, 02/08/17, 02/14/18, 02/13/19, 12/11/19, 02/12/20, 04/08/20, 06/10/20	APPROVAL DATE June 10, 2020	EFFECTIVE DATE June 26, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 01/04/12, 10/16/13, 10/14/15, 04/13/16, 02/08/17, 02/14/18, 02/13/19, 12/11/19, 02/12/20, 04/08/20, 06/10/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

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

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. 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**
    b. 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**
    c. 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**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **NOTE: The PREFERRED dose of Yervoy (ipilimumab), whenever used in combination with Opdivo (nivolumab), is 1 mg/kg, except for Small Cell Lung Cancer.**
3. **Melanoma**
    a. **NOTE: The preferred drugs, per NCH Policies & NCH Pathway, for the adjuvant therapy of completely resected stage III melanoma are nivolumab OR pembrolizumab.**
    b. The member has cutaneous melanoma and Yervoy (ipilimumab) is being used as any of the following:

i. For unresectable or metastatic melanoma:

A. First line therapy in combination with Opdivo (nivolumab) **OR**

B. Second line or subsequent therapy as a single agent or in combination with Opdivo (nivolumab) who have not received prior therapy with Yervoy (ipilimumab).

4. Small Cell Lung Cancer

a. The member has SCLC and Yervoy (ipilimumab) will be used in combination with Opdivo (nivolumab) as subsequent therapy and the member has not experienced disease progression on other PD-1/PDL-1 therapy.

5. Renal Cell Carcinoma

a. The member has a relapsed/metastatic or surgically unresectable disease **AND**

b. Yervoy (ipilimumab) will be used in combination with Opdivo (nivolumab) for 4 cycles followed by single agent nivolumab for Intermediate or Poor risk disease (as defined by the IMDC criteria Please see table below)

CRITERIA= Assign 1 point for each	**RISK CATEGORIES= RISK SCORE**
Time to systemic treatment less than 1 year from diagnosis	Favorable Risk = 0
Performance Status < 80% Karnofsky Scale	Intermediate Risk = 1-2
Hemoglobin < LLN; <12 g/dL	Poor Risk= 3-6
Calcium > ULN; > 12 mg/dL	
Neutrophils > ULN	
Platelets > ULN	

6. Colorectal Cancer

a. The member has unresectable/metastatic/recurrent microsatellite instability-high (MSI-H) or mismatch repair deficient[dMMR] colorectal cancer that has progressed following prior treatment with a fluoropyrimidine, oxaliplatin, and irinotecan **AND**

b. Yervoy (ipilimumab) is being used in combination with Opdivo (nivolumab) **AND**

c. Yervoy is being used for a total of 4 cycles only.

7. Hepatocellular Carcinoma (HCC)

a. **NOTE: Yervoy (ipilimumab) is not a preferred drug per NCH Policy or NCH Pathway for the treatment of hepatocellular carcinoma. Please refer to the NCH Pathway document for the most current recommended therapies for hepatocellular carcinoma.**

8. Non-Small Cell Lung Cancer

a. **NOTE: The combination of [Yervoy (ipilimumab + Opdivo(nivolumab)] for metastatic Non-Small Cell Lung Cancer, in the first line/subsequent line setting, is a Non-Preferred combination per NCH Policy and NCH Pathway. Please refer to the NCH**

Pathway document for the most current recommended regimens/agent for metastatic Non- Small Cell Lung Cancer.

III. EXCLUSION CRITERIA

1. Members who experience severe or life-threatening reactions to Yervoy (ipilimumab) including any moderate immune mediated adverse events or symptomatic endocrinopathy.
2. Disease progression while taking Yervoy (ipilimumab).
3. Dosing exceeds single dose limit of Yervoy (ipilimumab) 3mg/kg when Yervoy is being used as a single agent.
4. Dosing Exceeds 1 mg/kg when Yervoy (ipilimumab) is being given in combination with nivolumab.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert and/or ASCO guidelines for management of immunotherapy toxicities.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Yervoy prescribing information. Princeton, NJ. Bristol-Myers Squibb Company 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.