Clinical Policy: Ipilimumab (Yervoy)

Reference Number: CP.PHAR.319
Effective Date: 04.17.18
Last Review Date: 05.22
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ipilimumab (Yervoy®) is a human cytotoxic T-lymphocyte antigen 4 (CTLA-4)-blocking antibody.

FDA Approved Indication(s)

Yervoy is indicated for:

- **Unresectable or metastatic melanoma**
  - Treatment of unresectable or metastatic melanoma in adults and pediatric patients 12 years and older
  - Treatment of unresectable or metastatic melanoma in combination with nivolumab in adult patients
- **Adjuvant treatment of melanoma**
  - Patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy
- **Renal cell carcinoma (RCC)**
  - Treatment of patients with intermediate or poor risk, previously untreated advanced RCC, in combination with nivolumab
- **Colorectal cancer (CRC)**
  - Treatment of adult and pediatric patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, in combination with nivolumab*
- **Hepatocellular carcinoma (HCC)**
  - In combination with nivolumab, the treatment of patients with HCC who have been previously treated with sorafenib*
- **Non-small cell lung cancer (NSCLC)**
  - In combination with nivolumab, for the first-line treatment of adult patients with metastatic NSCLC whose tumors express programmed death-ligand 1 (PD-L1) ≥ 1% as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
  - In combination with nivolumab and 2 cycles of platinum-doublet chemotherapy, for the first-line treatment of adult patients with metastatic or recurrent NSCLC, with no EGFR or ALK genomic tumor aberrations
- **Malignant pleural mesothelioma**
  - Treatment of adult patients with unresectable malignant pleural mesothelioma, as first-line treatment in combination with nivolumab.

*This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Yervoy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Melanoma (must meet all)**:**

1. Diagnosis of unresectable, metastatic, or lymph node positive melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Prescribed in one of the following ways (a or b):
   a. As a single agent;
   b. In combination with Opdivo®, Keytruda®, or Imlygic®,* and both of the following (i and ii):
      i. Member has unresectable or metastatic melanoma;
      ii. Age ≥ 18 years;
      **Prior authorization may be required for Opdivo, Keytruda, and Imlygic*
5. Request meets one of the following (a, b, or c):*
   a. Unresectable or metastatic disease: Dose does not exceed 3 mg per kg every 3 weeks for a maximum of 4 doses;
   b. Adjuvant treatment: Dose does not exceed 10 mg/kg every 3 weeks for 4 doses, followed by 10 mg/kg every 12 weeks for up to 3 years;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Renal Cell Carcinoma (must meet all)**:**

1. Diagnosis of advanced or metastatic RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Prescribed in combination with Opdivo;*
   **Prior authorization may be required for Opdivo*
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg/kg IV every 3 weeks for a maximum of 4 doses;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 16 weeks (maximum of 4 doses)

C. Colorectal Cancer (must meet all)**:**
1. Diagnosis of MSI-H or dMMR CRC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Disease is unresectable or metastatic;
5. Prescribed in combination with Opdivo;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg/kg IV every 3 weeks for a maximum of 4 doses;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 16 weeks (maximum of 4 doses)

D. Hepatocellular Carcinoma (must meet all):
1. Diagnosis of HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member has previously received Nexavar®, Lenvima®, or Tecentriq® + bevacizumab (*Mvasi® and Zirabev™ are preferred*);
   **Prior authorization may be required for Nexavar, Lenvima, Tecentriq, and bevacizumab*
5. Prescribed in combination with Opdivo;
   **Prior authorization may be required for Opdivo*
6. Documentation of Child-Pugh Class A status;
7. Member has not had previous treatment with a checkpoint inhibitor (e.g., Opdivo, Keytruda®, Tecentriq®, Imfinzi®);
8. Request meets one of the following (a or b):*
   a. Dose does not exceed 3 mg/kg IV every 3 weeks for a maximum of 4 doses;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 16 weeks (maximum of 4 doses)

E. Non-Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of recurrent, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with Opdivo;*
   **Prior authorization may be required for Opdivo*
5. Member does not have contraindications to PD-1/PD-L1 inhibitor therapy (e.g., Opdivo, Keytruda, Tecentriq, Imfinzi) (*see Appendix D*);
6. Request meets one of the following (a, b, c, or d):*
   a. Disease mutation status is negative for actionable biomarkers (EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET), and member has not received prior systemic therapy for advanced disease;
   b. Disease mutation status is positive for EGFR S768I, L861Q, and/or G719X, and member has received prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib;

c. Disease mutation status is positive for ROS1 rearrangement, and member has received prior crizotinib, entrectinib, or ceritinib;
d. Disease mutation status is positive for EGFR exon 20, KRAS G12C, NRTK1/2/3, BRAF V600E, MET exon 14 skipping, or RET rearrangement;

7. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg/kg IV every 6 weeks in combination with Opdivo;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

   Approval duration: 6 months

F. Malignant Pleural Mesothelioma (must meet all)**:**

1. Diagnosis of unresectable malignant pleural mesothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with Opdivo;*

   **Prior authorization may be required for Opdivo.*
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg/kg IV every 6 weeks in combination with Opdivo;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

G. NCCN Compendium Indications (off-label) (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. MSI-H or dMMR small bowel adenocarcinoma;
   b. Metastatic uveal melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. For MSI-H/dMMR small bowel adenocarcinoma: Prescribed in combination with Opdivo;*
5. For uveal melanoma: Prescribed as a single agent or in combination with Opdivo;*

   **Prior authorization may be required for Opdivo*
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

H. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Melanoma - Unresectable or Metastatic

1. Reauthorization beyond 16 weeks is not permitted. Members must meet the initial approval criteria, at a minimum of 3 months since initial treatment discontinuation.

Approval duration: Not applicable

B. Renal Cell Carcinoma, Colorectal Cancer, Hepatocellular Carcinoma

1. Reauthorization beyond 16 weeks is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

C. Melanoma (Adjuvant Treatment), Non-Small Cell Lung Cancer, Malignant Pleural Mesothelioma (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Yervoy and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. For melanoma: New dose does not exceed 10 mg/kg every 12 weeks for up to 3 years;
   b. For NSCLC and malignant pleural mesothelioma: New dose does not exceed 1 mg/kg IV every 6 weeks in combination with Opdivo;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months or up to a total duration of 3 years (cutaneous melanoma) or 2 years (NSCLC, malignant pleural mesothelioma), whichever is less

D. NCCN Compendium Indications (off-label) (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Yervoy for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

E. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
BRAF: B-Raf proto-oncogene, serine/ threonine kinase
CRC: colorectal cancer
CTLA-4: cytotoxic T-lymphocyte antigen 4
dMMR: mismatch repair deficient
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
HCC: hepatocellular carcinoma
MET: mesenchymal-epithelial transition
MSI-H: microsatellite instability-high
PD-1: programmed death-1
PD-L1: programmed death-ligand 1
RCC: renal cell carcinoma
ROS1: ROS proto-oncogene 1

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Opdivo (nivolumab)	**MSI-H/dMMR small bowel adenocarcinoma** 3 mg/kg IV once every 3 weeks for four doses, then 3 mg/kg IV or 240 mg IV every 2 weeks with or without ipilimumab **Unresectable or metastatic melanoma** nivolumab 1 mg/kg every 3 weeks for four doses in combination with ipilimumab 3 mg/kg every 3 weeks, then nivolumab as a single agent until disease progression or unacceptable toxicity	RCC, HCC, melanoma: 480 mg/dose CRC, small bowel adenocarcinoma: 240 mg/dose
Nexavar (sorafenib)	**HCC** 400 mg PO BID	800 mg/day
Lenvima (lenvatinib)	**HCC** 12 mg PO QD (patients ≥ 60 kg) or 8 mg PO QD (patients < 60 kg)	12 mg/day
Tecentriq (atezolizumab) + bevacizumab (Avastin®, Mvasi, Zirabev)	**HCC** Tecentriq: 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks Bevacizumab: 15 mg/kg IV every 3 weeks	See regimen

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
platinum-containing regimens	**NSCLC – squamous cell carcinoma** paclitaxel + carboplatin dose varies **NSCLC – nonsquamous cell carcinoma** pemetrexed + [carboplatin or cisplatin] dose varies	Varies
EGFR S768I, L861Q, and/or G719X targeted therapies: afatinib, osimertinib, erlotinib, gefitinib, dacomitinib	**NSCLC** Varies	Varies
ROS1 targeted therapies: crizotinib, entrectinib, ceritinib	**NSCLC** Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications and Boxed Warnings

- Bristol-Myers Squibb was released from the REMS program for Yervoy in March 2015.
- Boxed warning(s): none reported
- Contraindication(s): none reported

Appendix D: General Information

- NCCN no longer recommends the use of Yervoy for small cell lung cancer or tumor mutation burden NSCLC.
- Per NCCN, contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents, or presence of an oncogene (i.e., EGFR exon 19 deletion or L858R, ALK rearrangements), which would predict lack of benefit.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Melanoma (adjuvant treatment)	10 mg/kg IV every 3 weeks for 4 doses, followed by 10 mg/kg every 12 weeks for up to 3 years or until documented disease recurrence or unacceptable toxicity.	10 mg/kg/dose
Melanoma (unresectable or metastatic)	Monotherapy: 3 mg/kg IV every 3 weeks for a total of 4 doses In combination with nivolumab: 3 mg/kg every 3 weeks with nivolumab 1 mg/kg for a maximum of	3 mg/kg/dose

Indication	Dosing Regimen	Maximum Dose
	4 doses or until unacceptable toxicity, whichever occurs earlier.	
RCC	Nivolumab 3 mg/kg IV, followed by ipilimumab 1 mg/kg IV on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240 mg IV every 2 weeks or 480 mg IV every 4 weeks	1 mg/kg/dose
CRC	Nivolumab 3 mg/kg IV, followed by ipilimumab 1 mg/kg IV on the same day, every 3 weeks for a maximum of 4 doses or until intolerable toxicity or disease progression, then nivolumab 240 mg IV every 2 weeks or 480 mg IV every 4 weeks	1 mg/kg/dose
HCC	Nivolumab 1 mg/kg IV, followed by ipilimumab 3 mg/kg IV on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240 mg IV every 2 weeks or 480 mg IV every 4 weeks	3 mg/kg/dose
NSCLC	In combination with nivolumab: nivolumab 3 mg/kg IV every 2 weeks and ipilimumab 1 mg/kg IV every 6 weeks until disease progression, unacceptable toxicity, or for up to 2 years in patients without disease progression In combination with nivolumab and platinum-doublet chemotherapy: nivolumab 360 mg IV every 3 weeks and ipilimumab 1 mg/kg IV every 6 weeks and histology-based platinum-doublet chemotherapy every 3 weeks for 2 cycles until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression	1 mg/kg/dose
Malignant pleural mesothelioma	1 mg/kg every 6 weeks with nivolumab 360 mg every 3 weeks until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression.	1 mg/kg/dose

VI. Product Availability

Single-use vials: 50 mg/10 mL, 200 mg/40 mL

VII. References

1. Yervoy Prescribing information. Princeton, NJ: Bristol-Myers Squibb Company; May 2021. Available at: https://packageinserts.bms.com/pi/pi_yervoy.pdf. Accessed January 28, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 28, 2022.

3. National Comprehensive Cancer Network. Malignant Pleural Mesothelioma Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mpm.pdf. Accessed January 28, 2022.
4. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 28, 2022.
5. Hellman MD, Paz-Ares L, Bernabe Caro R, et al. Nivolumab plus ipilimumab in advanced non-small-cell lung cancer. N Engl J Med. 2019 November; 381(21):2020-2031.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9228	Injection, ipilimumab, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Criteria added for new FDA indication: advanced renal cell carcinoma in combination with nivolumab; removed malignant pleural mesothelioma due to NCCN 2B recommendation status; added oncologist specialist requirement for all covered indications; summarized NCCN and FDA-approved uses for improved clarity; added up to a total tx duration of 3 years for cutaneous melanoma per PI; added failure of platinum-containing chemotx for SCLC per NCCN; allowed continuity of care for continued approval; clarified continued therapy language for unresectable or metastatic melanoma that reauthorization beyond 16 weeks is not permitted from reauthorization is not permitted; references reviewed and updated. Criteria added for new FDA indication: colorectal cancer in combination with nivolumab; references reviewed and updated.	07.24.18	08.18
2Q 2019 annual review: added coverage for malignant pleural mesothelioma; references reviewed and updated.	02.05.19	05.19
2Q 2020 annual review: added commercial line of business and revised HIM-medical benefit to HIM line of business; added NCCN compendium-supported indications of small bowel adenocarcinoma and uveal melanoma; condensed NCCN compendium-supported indications into one subsection; references reviewed and updated.	02.16.20	05.20
Added FDA-labeled indications of HCC and NSCLC in combination with Opdivo; references reviewed and updated.	06.23.20	08.20
RT4: FDA approved malignant pleural mesothelioma added. Ad hoc changes: melanoma unresectable/metastatic disease and lymph node positive disease criteria sets combined; for HCC,	11.18.20	02.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Lenvima added as a prior therapy option per NCCN; for NSCLC, single agent therapy for TMB positive tumor added and combination therapy for RET rearrangement added per NCCN, combination therapy changed from Yervoy and platinum doublet therapy to Yervoy plus/minus a platinum based regimen to accommodate NCCN recommended uses; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.		
2Q 2021 annual review: clarified RCC as "advanced or metastatic" per NCCN and prescribing information, removed SCLC from off-label indications as this is no longer supported by NCCN, and removed boxed warning from Appendix C per prescribing information; references reviewed and updated.	02.14.21	05.21
RT4: added new FDA-approved indication of combination treatment with Opdivo for melanoma; updated max dosing in melanoma criteria.	07.06.21	
2Q 2022 annual review: revisions made per NCCN – for melanoma, added pathway for use as a single agent or in combination with Keytruda or Imlygic; for HCC, added additional optional for prior use of Tecentriq + bevacizumab; for NSCLC, removed use in disease positive for tumor mutation burden biomarker, revised requirement for "progression on PD-1/PD-L1 inhibitors" to "no contraindications to PD-1/PD-L1 inhibitors", clarified criteria regarding disease mutation status (unknown status is no longer allowed, and prior targeted therapy is now only required for ROS1 and EGFR S768I, L861Q, and/or G719X mutations), and removed requirement for PD-L1 ≥ 1% as it is not necessary given allowable compendial uses; for uveal melanoma, added requirement that disease is metastatic; updated Appendix D to reflect NCCN's stance on SCLC and TMB NSCLC; references reviewed and updated.	01.28.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.