MEDICAL POLICY UPDATE

FOR PROFESSIONAL AND FACILITY PROVIDERS

HIGHMARK.

June 2021

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Policy

Revised Criteria for Wound Care Policy

NEWS FOR ALL PROVIDER TYPES

Highmark Blue Shield has revised criteria for E-31 Negative Pressure Wound Therapy Pumps/Vacuum Assisted Closure of Chronic Wounds.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is August 30, 2021.

Place of Service: Inpatient/Outpatient

Please refer to Medical Policy E-31 Negative Pressure Wound Therapy Pumps/Vacuum Assisted Closure of Chronic Wounds, for additional information.

Coverage Guidelines Established for Melphalan Flufenamide (Pepaxto)

NEWS FOR ALL PROVIDER TYPES

Highmark Blue Shield has established new guidelines for melphalan flufenamide (Pepaxto) to include the following:

Food and Drug Administration (FDA) Indications

Melphalan flufenamide (Pepaxto) may be considered medically necessary when the following criteria are met:

- Individual diagnosed with relapsed or refractory multiple myeloma; **and**
- Individual has received at least four (4) prior lines of therapy; **and**
- Disease is refractory to at least one (1) of **EACH** of the following:
    - Proteasome inhibitor; **and**
    - Immunomodulatory agent; **and**
    - CD38-directed monoclonal antibody; **and**
- Melphalan flufenamide (Pepaxto) will be given in combination with dexamethasone; **or**

National Comprehensive Cancer Network (NCCN) Recommendations

Multiple Myeloma

- Therapy in combination with dexamethasone for previously treated multiple myeloma for relapse or progressive disease in individuals who:
    - Have received at least four (4) prior lines of therapy; **and**
    - Individual has disease that is refractory to at least one (1) of **EACH** of the following:
        - Proteasome inhibitor; **and**
        - Immunomodulatory agent; **and**
        - CD38-directed monoclonal antibody

The use of melphalan flufenamide (Pepaxto) for all other indications is considered experimental/investigational, and therefore, non-covered. Peer reviewed literature does not support the use of melphalan flufenamide (Pepaxto) for any other indications

This Medical Policy will apply to professional and facility claims. The effective date was May 31,2021

Place of Service: Outpatient

Please refer to Medical Policy I-237, Melphalan flufenamide (Pepaxto), for additional information.

REMINDER: Cardiology & Radiology Imaging Coverage Guidelines

NEWS FOR ALL PROVIDER TYPES

Highmark Blue Shield is providing a reminder to all providers.

The Cardiology & Radiology Imaging coverage guidelines will be updated and take effect September 1, 2021. This applies to both professional provider and facility claims.

At that time, coverage guidelines can be accessed utilizing the live link from the medical policy website.

Oncology Compendia Guidelines

NEWS FOR ALL PROVIDER TYPES

Highmark Blue Shield will be updating how compendia recommendations are documented within medical policy. Upon subsequent review, Compendia indications will no longer be outlined within Highmark medical policies.

Compendia recommendations graded as 1, 2a or 2b for oncology indications will continue to be considered medically necessary. Compendia recommended indications that are identified as a Grade 3 rating will remain not medically necessary except under individual consideration or where mandated by an individual state.

The following statement indicating that the most current recommendations will be considered medically necessary will take the place of the currently represented compendia recommendations:

- [The drug which is the topic of the policy] may be considered medically necessary for treatment of any of the current category 1, 2A, or 2B compendia recommendations (NCCN, Clinical Pharmacology, MicroMedex, AHFS, Lexi-Comp, etc.).

This revised language will apply to professional providers and facility claims. The effective date is August 30, 2021.

Place of Service: Inpatient/Outpatient

Please refer to the Medical Policy for each specific oncology drug (if available), for additional information.

Coverage Guidelines Established for Melphalan Flufenamide (Pepaxto)

Highmark's Medicare Advantage product has established new guidelines for melphalan flufenamide (Pepaxto) to include the following:

FDA Indications

Melphalan flufenamide (Pepaxto) may be considered medically necessary when the following criteria are met:

- Individual diagnosed with relapsed or refractory multiple myeloma; **and**
- Individual has received at least four (4) prior lines of therapy; **and**
- Disease is refractory to at least one (1) of EACH of the following:
    - Proteasome inhibitor; **and**
    - Immunomodulatory agent; **and**
    - CD38-directed monoclonal antibody; **and**
- Melphalan flufenamide (Pepaxto) will be given in combination with dexamethasone; **or**

NCCN Recommendations

Multiple Myeloma

Melphalan flufenamid (Pepaxto) may be considered medically necessary for multiple myeloma hen the following criteria are met:

- Therapy in combination with dexamethasone for previously treated multiple myeloma for relapse or progressive disease in individuals who:
    - Have received at least four (4) prior lines of therapy; **and**
    - Individual has disease that is refractory to at least one (1) of **EACH** of the following:
        - Proteasome inhibitor; **and**
        - Immunomodulatory agent; **and**
        - CD38-directed monoclonal antibody

The use of melphalan flufenamide (Pepaxto) for all other indications will be considered not medically necessary and therefore, non-covered.

This revised Medical Policy will apply to professional providers and facility claims). The effective date was May 31, 2021.

Please refer to Medical Policy I-244, Melphalan flufenamide (Pepaxto), for additional information.

Coverage Guidelines Revised for Repository Corticotropin Injection (Acthar Gel)

Highmark's Medicare Advantage product has revised coverage criteria for Repository Corticotropin Injection (Acthar® Gel). The updates include the following:

Multiple Sclerosis (MS)

- Individuals receiving Repository Corticotropin Injection (Acthar Gel) for exacerbations of MS will be required to be concurrently receiving immunomodulatory therapy (interferon beta, glatiramer acetate, dimethyl fumarate, fingolimod, teriflunomide).

Rheumatoid Arthritis (Including Juvenile)

- In select cases of rheumatoid arthritis or juvenile rheumatoid arthritis, the individual requires low-dose maintenance therapy will be required to be concurrently receiving maintenance therapy with at least one (1) of the following:
  - NSAID
  - DMARD (e.g methotrexate, leflunomide, sulfasalazine)
  - Biologic (e.g. adalimumab, etanercept, infliximab, tofacitinib)

Step Therapy – Preferred Products

- Corticosteroids (e.g. IV methylprednisolone, IV dexamethasone, or high dose oral steroids) are the preferred product required for individuals initiating new therapy for multiple sclerosis, rheumatic disorders (ankylosing spondylitis, psoriatic arthritis, juvenile rheumatoid arthritis, or rheumatoid arthritis), collagen diseases (systemic lupus erythematosus, systemic dermatomyositis, polymyositis), dermatologic diseases (severe erythema multiforme, Stevens-Johnson syndrome), allergic states (serum sickness, transfusion reaction due to serum protein reaction), ophthalmic diseases (keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation), symptomatic sarcoidosis, nephrotic syndrome, adrenal insufficiency, gout, or epileptic aphasia. Corticotropin (Acthar Gel) will be considered when the individual has a documented therapy failure after an adequate therapeutic trial of two (2) corticosteroid products or the preferred products have not been tolerated or are contraindicated. New therapy is defined as no previous utilization within the last 365 calendar days.

The Medical Policy will apply to both professional provider and facility claims. The effective date will be August 30, 2021.

Please refer to Medicare Advantage Medical Policy I-121, Repository Corticotropin Injection (Acthar Gel), for additional information.

Oncology Compendia Guidelines

NEWS FOR ALL PROVIDER TYPES

MA MEDICARE ADVANTAGE

Highmark's Medicare Advantage product will be updating how compendia recommendations are documented within medical policy. Upon subsequent review, Compendia indications will no longer be outlined within Highmark medical policies.

Compendia recommendations graded as 1, 2a or 2b for oncology indications will continue to be considered medically necessary. Compendia recommended indications that are identified as a Grade 3 rating will remain not medically necessary except under individual consideration or where mandated by an individual state.

The following statement indicating that the most current recommendations will be considered medically necessary will take the place of the currently represented compendia recommendations:

- [The drug which is the topic of the policy] may be considered medically necessary for treatment of any of the current category 1, 2A, or 2B compendia recommendations (NCCN, Clinical Pharmacology, MicroMedex, AHFS, Lexi-Comp, etc.).

This revised language will apply to professional providers and facility claims. The effective date is August 30, 2021.

Please refer to the Medicare Advantage Medical Policy for each specific oncology drug (if available), for additional information.

Comments on these new medical policies?

We want to know what you think about our new medical policy changes. Send us an email with any questions or comments that you may have on the new medical policies in this edition of *Medical Policy Update*.

Write to us at **medicalpolicy@highmark.com**.

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About this newsletter

Medical Policy Update is the monthly newsletter for most health care professionals (and office staff) and facilities who participate in our networks and submit claims to Highmark using the 837P HIPAA transaction or the CMS 1500 form, or the 837I HIPAA transaction.

Medical Policy Update focuses only on medical policy and claims administration updates, including coding guidelines and procedure code revisions, and is the sole source for this information. For all other news, information and updates, be sure to read *Provider News*, available on the Provider Resource Center at **www.highmarkblueshield.com**.

Inquiries about Eligibility, Benefits, Claims Status or Authorizations

For inquiries about eligibility, benefits, claim status or authorizations, Highmark Blue Shield encourages providers to use the electronic resources available to them - NaviNet® and the applicable HIPAA transactions – prior to placing a telephone call to the Provider Service Center at 1-866-803-3708.

Acknowledgement