Highmark Blue Cross Blue Shield has established new coverage criteria for pertuzumab, trastuzumab, and hyaluronidase-zzxf (Phesgo™) fixed dose subcutaneous formulation.

The use of pertuzumab, trastuzumab, and hyaluronidase (Phesgo) may be considered medically when the presence of the HER2-overexpression is confirmed by the following: HER2-overexpression must be verified by ANY ONE of the following US Food and Drug Administration (FDA) approved diagnostic tests:

- An immunohistochemical (IHC) assay with a result of 3+ (positive); or
- A positive fluorescence in situ hybridization (FISH) test (ratio greater than 2.0); or
- Single-probe in situ hybridization (ISH) test with average HER2 copy number 6.0 signals/cell or greater; or
- Dual-probe ISH test HER2/CEP17 (chromosome enumeration probe 17) ratio 2.0 or greater; or HER2/CEP17 ratio less than 2.0 AND average HER2 copy number 6.0 signals/cell or greater.

Confirmatory tests should be performed for borderline results as follows:

- If IHC assay has a result of 2+, confirm with ISH test of the same sample or a new test with IHC or ISH (if new sample available); or

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Note: This publication may contain certain administrative requirements, policies, procedures, or other similar requirements of Highmark Inc. (or changes thereto) which are binding upon Highmark Inc. and its contracted providers. Pursuant to their contract, Highmark Inc. and such providers must comply with any requirements included herein unless and until such item(s) are subsequently modified in whole or in part.
• If FISH test has a HER2 gene/chromosome 17 ratio of 1.8-2.0, confirm with FISH retest; additional cell counting and recalculation of the ratio; or IHC assay; or If single-probe ISH assay has an average HER2 copy number result of 4.0 to less than 6.0 signals/cell, confirm with dual-probe ISH or with IHC (if same sample), or with a new ISH or IHC (if new sample available); or If dual-probe ISH assay has a HER2/CEP17 ratio less than 2.0 and an average HER2 copy number result of 4.0 to less than 6.0 signals/cell, confirm with one of the following: IHC (if same sample), alternative ISH chromosome 17 probe, or order a new test with ISH or IHC (if new sample available).

FDA Indications
The use of pertuzumab, trastuzumab, and hyaluronidase (Phesgo) may be considered medically necessary in individuals 18 years of age and older for the following:

• As therapy in combination with chemotherapy for EITHER of the following:
  o Neoadjuvant treatment of individuals with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer; or
  o Adjuvant treatment of individuals with HER2-positive early breast cancer at high risk of recurrence; or

• As therapy in combination with docetaxel for the treatment of individuals with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

National Comprehensive Cancer Network (NCCN) Recommendations
The use of pertuzumab, trastuzumab, and hyaluronidase (Phesgo) may be considered medically necessary in individuals 18 years of age and older for the following:

• As a substitute anywhere that the combination of intravenous pertuzumab and intravenous trastuzumab are given as part of systemic therapy.

This new medical policy will apply to both professional provider and facility claims. The effective date was September 7, 2020.

Please refer to Medical Policy I-225, Pertuzumab, trastuzumab, and hyaluronidase-zzxf (Phesgo), for additional information.

Place of Service: Outpatient
Coverage Criteria Revised for Autonomic Nervous System Function Testing

Highmark Blue Cross Blue Shield has revised criteria for Autonomic Nervous System (ANS) Function Testing.

Autonomic function testing, consisting of a battery of tests in several domains may be considered medically necessary when used as a diagnostic tool to evaluate symptoms indicative of vasomotor instability, such as hypotension, orthostatic tachycardia, and hyperhidrosis after more common causes have been excluded by other testing, and the ANS testing is directed at establishing a more accurate or definitive diagnosis or contributing to clinically useful and relevant medical decision making for one of the following indications:

- To diagnose the presence of autonomic neuropathy in an individual with signs or symptoms suggesting autonomic neuropathy or to evaluate the severity and distribution of a diagnosed autonomic neuropathy in the following conditions:
  - Diabetic autonomic neuropathy; or
  - Amyloid neuropathy; or
  - Idiopathic neuropathy; or
  - Pure autonomic failure; or
  - Multiple system atrophy (Shy-Drager syndrome); or
- To differentiate the diagnosis between certain complicated variants of syncope from other causes of loss of consciousness; or
- To evaluate inadequate response to beta blockade in vasodepressor syncope; or
- To evaluate distressing symptoms in an individual with a clinical picture suspicious for distal small fiber neuropathy in order to diagnose the condition; or
- To differentiate the cause of postural orthostatic tachycardia syndrome; or
- To evaluate change in type, distribution or severity of autonomic deficits in individuals with autonomic failure; or
- To evaluate the response to treatment in individuals with autonomic failure who demonstrate a change in clinical exam; or
- To diagnose axonal neuropathy or suspected autonomic neuropathy in the symptomatic individual; or
- To evaluate and treat individuals with recurrent unexplained syncope to demonstrate autonomic failure, after more common causes have been excluded by other standard testing.

The Sudoscan test will be added as not medically necessary.

This revised Medical Policy will apply to professional providers and/or facility claims. The effective date is November 30, 2020.

Place of Service: Outpatient

Please refer to Medical Policy M-61, Autonomic Nervous System Function Testing, for additional information.
Coverage Guidelines Revised for Private Duty Nursing

Highmark Blue Cross Blue Shield has revised coverage guidelines for Private Duty Nursing. This will apply to both professional provider and facility claims. The effective date is November 30, 2020.

Place of Service: Outpatient

Please refer to Medical Policy Q-4, Private Duty Nursing, for additional information.
Coverage Guidelines Established for Pertuzumab, Trastuzumab, and Hyaluronidase-zzxf (Phesgo)

Highmark’s Medicare Advantage products have established new guidelines for pertuzumab, trastuzumab, and hyaluronidase-zzxf (Phesgo™) fixed dose subcutaneous formulation.

The use of pertuzumab, trastuzumab, and hyaluronidase (Phesgo) may be considered medically when the presence of the HER2-overexpression is confirmed by the following: HER2-overexpression must be verified by ANY ONE of the following FDA approved diagnostic tests:

- An immunohistochemical (IHC) assay with a result of 3+ (positive); or
- A positive fluorescence in situ hybridization (FISH) test (ratio greater than 2.0); or
- Single-probe in situ hybridization (ISH) test with average HER2 copy number 6.0 signals/cell or greater; or
- Dual-probe ISH test HER2/CEP17 (chromosome enumeration probe 17) ratio 2.0 or greater; or HER2/CEP17 ratio less than 2.0 AND average HER2 copy number 6.0 signals/cell or greater.

Confirmatory tests should be performed for borderline results as follows:

- If IHC assay has a result of 2+, confirm with ISH test of the same sample or a new test with IHC or ISH (if new sample available); or
- If FISH test has a HER2 gene/chromosome 17 ratio of 1.8-2.0, confirm with FISH re-test; additional cell counting and recalculation of the ratio; or IHC assay; or
- If single-probe ISH assay has an average HER2 copy number result of 4.0 to less than 6.0 signals/cell, confirm with dual-probe ISH or with IHC (if same sample), or with a new ISH or IHC (if new sample available); or
- If dual-probe ISH assay has a HER2/CEP17 ratio less than 2.0 and an average HER2 copy number result of 4.0 to less than 6.0 signals/cell, confirm with one of the following: IHC (if same sample), alternative ISH chromosome 17 probe, or order a new test with ISH or IHC (if new sample available).

Food and Drug Administration (FDA) Indications

The use of pertuzumab, trastuzumab, and hyaluronidase (Phesgo) may be considered medically necessary in individuals 18 years of age and older for the following:

- As therapy in combination with chemotherapy for EITHER of the following:
  - Neoadjuvant treatment of individuals with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer; or
  - Adjuvant treatment of individuals with HER2-positive early breast cancer at high risk of recurrence; or
- As therapy in combination with docetaxel for the treatment of individuals with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
National Comprehensive Cancer Network (NCCN) Recommendations
The use of pertuzumab, trastuzumab, and hyaluronidase (Phesgo) may be considered medically necessary in individuals 18 years of age and older for the following:

- As a substitute anywhere that the combination of intravenous pertuzumab and intravenous trastuzumab are given as part of systemic therapy.

This new Medical Policy will apply to professional providers and facility claims. The effective date was September 7, 2020.

Please refer to Medicare Advantage Medical Policy I-232, Pertuzumab, trastuzumab, and hyaluronidase-zzxf (Phesgo), for additional information.

Coverage Guidelines Revised for Rituximab (Rituxan), Rituximab Biosimilars, and Rituximab and Hyaluronidase Human (Rituxan Hyqela)

Highmark’s Medicare Advantage products have revised coverage criteria for rituximab (Rituxan®) and rituximab biosimilars [rituximab-abbs (Truxima®) and rituximab-pvvr (Ruxience™)] as follows:

- Define adult as individuals 18 years of age or older.
- Align with current 2b or higher compendia supported off-label indications by removing the following:
  - Hepatitis C Virus–Associated cryoglobulinemic vasculitis
  - Neuromyelitis optica
  - Systemic lupus erythematosus
  - Lupus nephritis
  - Systemic sclerosis (scleroderma)
  - Idiopathic membranous nephropathy
  - Microscopic polyarteritis nodosa
- Updating rituximab indications which may be considered medically necessary as:
  - Treatment for pediatric Evans syndrome refractory to immunosuppressive therapy; or
  - Treatment for individuals 18 years of age or older with who have failed to respond to, or are intolerant to, another immunosuppressant (e.g. methotrexate) with refractory idiopathic inflammatory myopathy; or
  - Prophylaxis for prevention of Epstein Barr virus infection in pediatric individuals undergoing hematopoietic stem cell transplant
  - Treatment for pediatric individuals with previously treated primary and secondary immune thrombocytopenia
  - Treatment for remission induction and maintenance of remission in pediatric individuals who have refractory, steroid-dependent or steroid-resistant minimal change disease
  - Treatment for individuals 18 years of age or older with primary progressive multiple sclerosis who have gadolinium brain lesions at baseline and have failed treatment with ocrelizumab
  - Treatment of relapsing remitting multiple sclerosis when the individuals has experienced therapeutic failure, intolerance, or contraindication to two alternative drug therapies indicated for the treatment of multiple sclerosis (e.g. Avonex, Aubagio, Gilenya, etc.)
- Treatment for individuals 18 years if age or older with myasthenia gravis refractory to conventional therapy (e.g., azathioprine, corticosteroids, immunosuppressants, plasma exchange, IV immunoglobulin, thymectomy)
- Treatment of moderate to severe treatment-refractory pemphigus vulgaris (PV) in adult individuals 18 years or older
- Treatment for individuals 18 years of age or older with pemphigus foliaceus in combination with a tapering course of corticosteroids
- Treatment for individuals 18 years of age or older with primary Sjögren’s syndrome as a one (1) time course of treatment over 15 days; or
- Treatment as add-on therapy for systemic lupus erythematosus refractory to immunosuppressive therapy; or
- Treatment for individuals 18 years of age or older with idiopathic thrombocytopenic purpura refractory to first-line therapy (e.g., corticosteroids, IV immune globulin, splenectomy, etc.) who are at risk of bleeding (grade 2C); or
- Treatment in combination with steroids and plasma exchange in individuals 18 years of age or older with refractory thrombotic thrombocytopenic purpura (i.e., lack of response to plasma exchange therapy and glucocorticoids); or
- Update the following National Comprehensive Cancer Network (NCCN) recommendations:
  - Intra-cerebrospinal fluid (CSF) treatment for leptomeningeal metastases from lymphomas for:
    - Primary treatment in individuals with good risk status (KPS greater than or equal to 60, no major neurologic deficits, minimal systemic disease, and reasonable systemic treatment options if needed)
    - Maintenance treatment in individuals with negative CSF cytology or in clinically stable individuals with persistently positive CSF cytology; or
    - Treatment in individuals with positive CSF cytology that have progressed after receiving prior treatment; or
  - Induction therapy for primary central nervous system (CNS) lymphoma:
    - As a single agent if individual is unsuitable for or intolerant to high-dose methotrexate; or
    - In combination with temozolomide if individual is unsuitable for or intolerant to high-dose methotrexate; or
    - In combination with lenalidomide if individual is unsuitable for or intolerant to high-dose methotrexate; or
  - Consider as intra-CSF therapy for primary CNS lymphoma if CSF positive or spinal MRI positive as:
    - Part of induction therapy; or
    - Treatment alone or in combination with systemic chemotherapy for relapsed or refractory disease in individuals with prior WBRT; or
  - Treatment as a single agent or in combination with temozolomide or lenalidomide for relapsed or refractory primary CNS lymphoma:
    - May be considered in individuals who received prior whole brain radiation therapy (RT); or
    - In individuals who received a prior high-dose methotrexate-based regimen without prior RT; or
    - In combination with whole brain RT or involved field RT in individuals who received a prior high-dose methotrexate-based regimen without prior RT after no response or short response duration (less than 12 months) to prior regimen; or
    - In individuals who received prior high-dose chemotherapy with stem cell rescue; or
o Treatment in combination with high-dose methotrexate with or without ibrutinib for relapsed or refractory primary CNS lymphoma:
  - In individuals who received prior whole brain radiation; or
  - In individuals who received a prior high-dose methotrexate-based regimen without prior radiation therapy (RT) and a previous long response duration (≥12 months) to prior regimen; or

o Second-line therapy or subsequent therapy for relapse of AIDS-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and HHV8-positive DLBCL, not otherwise specified (NOS) In non-candidates for transplant as a single agent, in combination with polatuzumab vedotin-piql with or without bendamustine (greater than or equal to two (2) prior therapies), with lenalidomide (for non-germinall center DLBCL) or bendamustine, with gemcitabine and vinorelbine, or as a component of CEPP (cyclophosphamide, etoposide, prednisone, and procarbazine), dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin), CEOP (cyclophosphamide, etoposide, vincristine, and prednisone), GDP, or GemOX regimen with rituximab.

o Induction therapy for low-risk Burkitt Lymphoma for individuals less than 60 years of age as a component of:
  - CODOX-M (cyclophosphamide, doxorubicin, and vincristine, with intrathecal methotrexate and cytarabine followed by high-dose systemic methotrexate) regimen (original or modified) regimen with rituximab; or
  - Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin) regimen with rituximab and intrathecal methotrexate; or
  - HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) alternating with high-dose methotrexate and cytarabine regimen with rituximab (regimen includes intrathecal therapy); or

o Induction therapy for high-risk Burkitt Lymphoma in individuals less than 60 years of age as a component of:
  - CODOX-M (cyclophosphamide, doxorubicin, and vincristine, with intrathecal methotrexate and cytarabine followed by high-dose systemic methotrexate) regimen (original or modified) alternating with IVAC (ifosfamide, cytarabine, etoposide, and intrathecal methotrexate) regimen with rituximab; or
  - Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin) regimen with rituximab and intrathecal methotrexate for individuals not able to tolerate aggressive therapy; or
  - Hyper-CVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) alternating with high-dose methotrexate and cytarabine regimen with rituximab (regimen includes intrathecal therapy); or

o Induction therapy for low-risk and high-risk Burkitt Lymphoma in individuals 60 years of age or older as a component of dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin) regimen with rituximab and intrathecal methotrexate; or

o Used for Burkitt Lymphoma as a component of dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin) regimen with rituximab and intrathecal methotrexate, RICE (rituximab, ifosfamide, carboplatin, and etoposide) regimen with intrathecal methotrexate if not previously given, RIVAC (rituximab, ifosfamide, cytarabine, and etoposide) regimen with intrathecal methotrexate if not previously given:
  - As second-line therapy for relapse of Burkitt lymphoma greater than 6-18 months following appropriate first-line therapy; or
- For individuals with partial response to second-line therapy as additional therapy (if not previously given) for relapse or refractory disease; or
- Second-line therapy for patients with disease relapse >6-18 months after appropriate first-line therapy or for individuals with partial response to second-line therapy as additional therapy (if not previously given) for relapsed or refractory Burkitt Lymphoma:
  - As a component of RGDP (rituximab, gemcitabine, dexamethasone, and cisplatin) regimen; or
  - As a component of high-dose cytarabine with rituximab regimen; or
- Remove as first-line therapy for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) without del(17p)/TP53 mutation in frail individuals with significant comorbidity who are not able to tolerate purine analogs:
  - In combination with chlorambucil (preferred regimen**); or
  - In combination with high-dose methylprednisolone; or
- Include as first-line therapy for CLL/SLL without del(17p)/TP53 mutation in frail individuals with significant comorbidities (CrCl less than 70 ml/min) who have indications for treatment:
  - In combination with high-dose methylprednisolone; or
  - As a single agent; or
- First-line therapy in combination with bendamustine for CLL/SLL without del(17p)/TP53 mutation in individuals greater than or equal to 65 years of age and younger patients with or without significant comorbidities who have indications for treatment (not recommended for frail patients); or
- First-line therapy for CLL/SLL without del(17p)/TP53 mutation in individuals age less than 65 years without significant comorbidities who have indications for treatment:
  - In combination with ibrutinib; or
  - In combination with high-dose methylprednisolone; or
  - As a component of PCR (pentostatin, cyclophosphamide, and rituximab) regimen; or
- First-line therapy for CLL/SLL with del(17p)/TP53 mutation in combination with alemtuzumab or high-dose methylprednisolone; or
- First-line therapy for CLL/SLL without del(17p)/TP53 mutations in individuals less than 65 years of age without significant comorbidities who have indications for treatment as a component of:
  - FCR (fludarabine, cyclophosphamide, and rituximab) regimen (for individuals with IGHV mutated CLL); or
  - Fludarabine and rituximab (FR) regimen [not recommended for CLL with del(11q)]; or
- Therapy for relapsed or refractory CLL/SLL without del(17p)/TP53 mutation in frail individuals with significant comorbidity or age greater than or equal to 65 years and younger individuals with significant comorbidities:
  - In combination with idelalisib or venetoclax; or
  - As a single agent in a dose-dense regimen; or
  - In combination with alemtuzumab, chlorambucil, lenalidomide, or high-dose methylprednisolone; or
  - As a component of reduced-dose FCR (fludarabine, cyclophosphamide, and rituximab) or reduced-dose PCR (pentostatin, cyclophosphamide, and rituximab) regimen; or
- Therapy for relapsed or refractory CLL/SLL without del(17p)/TP53 mutation in individuals greater than or equal to 65 years of age or younger individuals with
significant comorbidities (CrCl less than 70 ml/min) in combination with
bendamustine and with or without ibritinib or idelalisib (not recommended for
frail individuals); or

- Therapy for relapsed or refractory CLL/SLL without del(17p)/TP53 mutation in
  individuals less than 65 years without significant comorbidities:
  - In combination with idelalisib or venetoclax; or
  - In combination with alemtuzumab, bendamustine with or without ibritinib
    or idelalisib, high-dose methylprednisolone, or lenalidomide; or
  - As a component of FCR (fludarabine, cyclophosphamide, and rituximab)
    or PCR (pentostatin, cyclophosphamide, and rituximab) regimen; or

- Therapy for relapsed or refractory CLL/SLL with del(17p)/TP53 in combination
  with:
  - Idelalisib or venetoclax; or
  - Alemtuzumab, lenalidomide, or high-dose methylprednisolone; or

- Initial therapy for histologic (Richter's) transformation to DLBCL (clonally related
  or unknown clonal status) as a component of:
  - RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and
    prednisone) regimen; or
  - Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide,
    and doxorubicin) with rituximab regimen; or
  - HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and
dexamethasone) with rituximab regimen alternating with high-dose
  methotrexate and cytarabine regimen; or
  - OFAR (oxaliplatin, fludarabine, cytarabine, and rituximab) regimen; or

- Second-line or subsequent therapy for partial response, no response, relapsed,
  progressive, or refractory DLBCL in individuals with intention to proceed to
  transplant as a component of:
  - DHAP (dexamethasone, cisplatin, and cytarabine) regimen with rituximab;
    or
  - DHAX (dexamethasone, cytarabine, and oxaliplatin) regimen with
    rituximab,
  - ESHAP (etoposide, methylprednisolone, cytarabine, and cisplatin)
    regimen with rituximab; or
  - GDP (gemcitabine, dexamethasone, and cisplatin or gemcitabine,
dexamethasone, and carboplatin) regimen with rituximab; or
  - GemOX (gemcitabine and oxaliplatin) regimen with rituximab; or
  - ICE (ifosfamide, carboplatin, and etoposide) regimen with rituximab; or
  - MINE (mesna, ifosfamide, mitoxantrone, and etoposide) regimen with
    rituximab; or

- Second-line or subsequent therapy for partial response, no response, relapsed,
  progressive, or refractory DLBCL in non-candidates for transplant:
  - As a single agent; or
  - In combination with lenalidomide (non-germinal center lymphoma); or
  - In combination with bendamustine; or
  - In combination with Polatuzumab vedotin-piiq with or without
    bendamustine after greater than or equal to two (2) prior therapies; or
  - As a component of CEPP (cyclophosphamide, etoposide, prednisone,
    and procarbazine) with rituximab regimen; or
  - As a component of dose-adjusted EPOCH (etoposide, prednisone,
vincristine, cyclophosphamide, and doxorubicin) with rituximab regimen;
    or
  - As a component of CEOP (cyclophosphamide, etoposide, vincristine, and
    prednisone) with rituximab regimen; or
  - As a component of GDP with rituximab regimen; or
- As a component of GemOX with rituximab regimen; or
- As a component of gemcitabine and vinorelbine regimens with rituximab; or

Treatment of primary cutaneous DLBCL, leg type as first-line with involved site radiation therapy or as second-line therapy (if not previously received) for solitary regional T 1-2 disease, or as first-line therapy for generalized cutaneous, T3 disease:
- As a component of RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) regimen; or

Treatment of primary cutaneous DLBCL, leg type as first-line with involved site radiation therapy or as second-line therapy (if not previously received) for solitary regional T 1-2 disease, or as first-line therapy for generalized cutaneous, T3 disease in individuals with poor left ventricular function as a component of:
- RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, and procarbazine) regimen; or
- RCDOP (rituximab, cyclophosphamide, liposomal doxorubicin, vincristine, and prednisone) regimen; or
- Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin) regimen with rituximab; or
- RCEOP (rituximab, cyclophosphamide, etoposide, vincristine, and prednisone) regimen; or
- RGCV (rituximab, gemcitabine, cyclophosphamide, vincristine, and prednisolone) regimen; or

Treatment of primary cutaneous DLBCL, leg type as first-line with involved site radiation therapy or as second-line therapy (if not previously received) for solitary regional T 1-2 disease, or as first-line therapy for generalized cutaneous, T3 disease for very frail individuals and individuals greater than 80 years of age with comorbidities as a component of:
- RCEPP regimen; or
- RCDOP regimen; or
- R-mini-CHOP; or
- RGCV regimen.

Remove as second-line or subsequent therapy for partial response, no response, relapsed, progressive, or refractory primary cutaneous DLBCL, leg type:
- As a component of DHAP (dexamethasone, cisplatin, and cytarabine), DHAX (dexamethasone, cytarabine, and oxaliplatin), ESHAP (etoposide, methylprednisolone, cytarabine, and cisplatin), GDP (gemcitabine, dexamethasone, and cisplatin or gemcitabine, dexamethasone, and carboplatin), GemOX (gemcitabine and oxaliplatin), ICE (ifosfamide, carboplatin, and etoposide), or MINE (mesna, ifosfamide, mitoxantrone, and etoposide) regimen with rituximab in individuals with intention to proceed to transplant; or
- As a single agent, in combination with lenalidomide (non-germinal center lymphoma) or bendamustine, or as a component of CEPP (cyclophosphamide, etoposide, prednisone, and procarbazine), dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin), CEOP (cyclophosphamide, etoposide, vincristine, and prednisone), GDP, GemOX, or gemcitabine in noncandidates for transplant.

Used in individuals with indications with hairy cell leukemia for treatment in combination with:
- Cladribine for less than complete response or relapse within two (2) years of complete response following initial treatment with pentostatin; or
Pentostatin for less than complete response or relapse within two (2) years of complete response following initial treatment with cladribine; or Vemurafenib for progression after therapy for relapsed/refractory disease; or

Add the following NCCN indications

- Pediatric aggressive mature B-cell lymphomas
- Update the following NCCN indications
- CNS cancers – leptomeningeal metastases
- CNS cancers – primary CNS lymphoma
- Nodular lymphocyte – predominant Hodgkin lymphoma
- AIDS-related B-cell lymphomas
- Burkitt lymphoma
- CLL/SLL
- Diffuse large B-cell lymphoma
- High-grade B-cell lymphomas
- Follicular lymphoma
- Gastric MALT lymphoma
- Nongastric MALT lymphoma (noncutaneous)
- Nodal marginal zone lymphoma
- Mantle cell lymphoma
- Immune checkpoint inhibitor-related toxicities
- Splenic marginal zone lymphoma
- Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma

The Medical Policy will apply to both professional provider and facility claims. The effective date is November 30, 2020.

Please refer to Medical Policy I-38, Rituximab (Rituxan), Rituximab Biosimilars, and Rituximab and Hyaluronidase Human (Rituxan Hycela), 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.highmarkbcbs.com.

Inquiries about Eligibility, Benefits, Claims Status or Authorizations
For inquiries about eligibility, benefits, claim status or authorizations, Highmark Blue Cross 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 1-800-242-0514.

Acknowledgement
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