Clinical Policy: Rituximab (Rituxan), Rituxan/Hyaluronidase (Rituxan Hycela)

Reference Number: CP.PHAR.260
Effective Date: 07.01.16
Last Review Date: 11.18
Line of Business: Medicaid, HIM*

Coding Implications
Revision Log

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

Description

Rituximab (Rituxan®) is a human monoclonal immunoglobulin G-1 (IgG1) kappa antibody directed against the CD20 antigen.

Rituximab and hyaluronidase (Rituxan Hycela™) is a combination of rituximab and human hyaluronidase that is used to increase the dispersion and absorption of the co-administered drugs when given subcutaneously.

**For Health Insurance Marketplace (HIM),* *Rituxan Hycela is non-formulary and cannot be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

FDA Approved Indication(s)

Rituxan is indicated for the treatment of:

- Non-Hodgkin's lymphoma (NHL)
  - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
  - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as single-agent maintenance therapy
  - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line CVP (cyclophosphamide, vincristine, prednisone) chemotherapy
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens
- Chronic lymphocytic leukemia (CLL)
  - Previously untreated and previously treated CD20-positive CLL, in combination with fludarabine and cyclophosphamide (FC)
- Rheumatoid arthritis (RA)
  - Moderately- to severely- active RA in adult patients in combination with methotrexate (MTX) and after inadequate response to one or more tumor necrosis factor antagonist therapies
- Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA)
  - GPA and MPA in adult patients in combination with glucocorticoids
- Pemphigus Vulgaris (PV)

- Moderate to severe Pemphigus Vulgaris (PV) in adult patients.

Rituxan Hycela is indicated for the treatment of:

- Adult patients with follicular lymphoma (FL)
  - Relapsed or refractory, FL as a single agent
  - Previously untreated FL in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy
  - Non-progressing (including stable disease), FL as a single agent after first-line CVP chemotherapy
- Adult patients with diffuse large B-cell lymphoma (DLBCL)
  - Previously untreated DLBCL in combination with CHOP or other anthracycline-based chemotherapy regimens
- Adult patients with CLL
  - Previously untreated and previously treated CLL in combination with FC

Limitation(s) of use:

- Rituxan is not recommended for use in patients with severe, active infections.
- Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion.
- Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

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 Rituxan and Rituxan Hycela are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Hodgkin's Lymphoma *(includes Chronic Lymphocytic Leukemia)* (must meet all)**:**

1. Diagnosis of non-Hodgkin's lymphoma or any of its subtypes (*see Appendix E*);
2. Age ≥ 18 years;
3. If request is for Rituxan Hycela, member has received at least one full dose of Rituxan;
4. Request meets any of the following (a or b):
   a. Dose does not exceed (i or ii):
      i. Rituxan: 500 mg/m^2 per IV infusion (*see Section V for cycle regimens)*;
      ii. Rituxan Hycela: 1,600 mg/26,800 units SC (*see Section V for cycle regimens)*;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid – 6 months
HIM – 6 months for Rituxan *(Refer to HIM.PA.103 for Rituxan Hycela)*

B. Rheumatoid Arthritis (must meet all)**:**
1. Diagnosis of RA;
2. Request is for Rituxan;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a ≥ 3 consecutive month trial of at least ONE conventional disease-modifying antirheumatic drug [DMARD] (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of etanercept *(Enbrel® is preferred)* AND adalimumab *(Humira® is preferred)*, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
7. Rituxan will be administered in combination with MTX unless contraindicated or clinically significant adverse effects are experienced;
8. Dose does not exceed two-1,000 mg IV infusions separated by 2 weeks followed by two-1,000 mg IV infusions every 16 weeks.

Approval duration: 6 months

C. Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis (must meet all)**:**
1. Diagnosis of GPA or MPA;
2. Request is for Rituxan;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Rituxan will be administered in combination with glucocorticoid therapy;
6. Dose does not exceed 375 mg/m^2 weekly.

Approval duration: Up to 4 weeks total

D. Pemphigus Vulgaris (must meet all)**:**
1. Diagnosis of PV;
2. Request is for Rituxan;
3. Prescribed by or in consultation with a dermatologist;
4. Age ≥ 18 years;
5. Dose does not exceed:
   a. Initial: two-1,000 mg infusions separated by 2 weeks;
   b. Maintenance: 500 mg every 6 months (starting 12 months after initial dose).

Approval duration: 6 months

E. NCCN Compendium Indications (off-label) (must meet all)**:**
1. Diagnosis of one of the following (a, b, or c):

a. Primary CNS lymphoma;
b. Leptomeningeal metastases;
c. Nodular lymphocyte-predominant Hodgkin lymphoma;

2. Request is for Rituxan;
3. Prescribed by or in consultation with an oncologist;
4. For nodular lymphocyte-predominant Hodgkin Lymphoma, age ≥ 18;
5. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

F. Other diagnoses/indications

1. Members with any of the following diagnoses may be covered if the off-label criteria policy is met:
   a. Myasthenia gravis;
   b. Nephrotic syndrome;
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): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Documentation supports that member is currently receiving Rituxan or Rituxan Hycela for a covered oncology indication and has received this medication for at least 30 days;
2. Meets one of the following (a or b):
   a. Member is responding positively to therapy;
   b. Member has experienced relapse for PV;
3. If request is for a dose increase, request meets any of the following (a or b):
   a. New dose does not exceed (i or ii):
      i. Rituxan (a, b, c, or d):
         a) NHL: 500 mg/m^2 per IV infusion (*see Section V for cycle regimens)*;
         b) RA: Two-1,000 mg IV infusions every 16 weeks;
         c) GPA/MPA: 375 mg/m^2 IV weekly;
         d) PV (1 or 2):
            a. Relapse: 1,000 mg IV once then 500 mg IV 16 weeks later, then 500 mg IV every 6 months;
            b. Maintenance: 500 mg IV every 6 months (starting 12 months after initial dose);
      ii. Rituxan Hycela for NHL: 1,600 mg/26,800 units SC (*see Section V for cycle regimens)*;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: GPA/MPA: Up to 4 weeks total
All other indications: 12 months

B. 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. Members with any of the following diagnoses may be covered if the off-label criteria policy is met:
   a. Myasthenia gravis;
   b. Nephrotic syndrome;
3. 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): HIM.PHAR.21 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 – HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CHOP: cyclophosphamide, doxorubicin, vincristine, prednisone
CLL: chronic lymphocytic leukemia
CVP: cyclophosphamide, vincristine, prednisone
DLBCL: diffuse large B-cell lymphoma
DMARD: disease-modifying antirheumatic drug
FC: fludarabine and cyclophosphamide
FDA: Food and Drug Administration
FL: follicular lymphoma
GPA: granulomatosis with polyangiitis (Wegener's granulomatosis)
IgG1: immunoglobulin G-1
MALT: mucosa-associated lymphoid tissue
MPA: microscopic polyangiitis
MTX: methotrexate
NCCN: National Comprehensive Cancer Network
NHL: Non-Hodgkin's lymphoma
PV: pemphigus vulgaris
RA: rheumatoid arthritis
SLL: small lymphocytic lymphoma

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
fludarabine and cyclophosphamide (FC)	**CD20-positive CLL/SLL** Varies upon protocol and patient tolerance	Varies
cyclophosphamide, vincristine, prednisone (CVP)	**Other CD20-positive B-cell NHL lymphomas** Varies upon protocol and patient tolerance	Varies
cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP)	**Other CD20-positive B-cell NHL lymphomas** Varies upon protocol and patient tolerance	Varies
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD	5 mg/kg/day
leflunomide (Arava®)	**RA** 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
methotrexate (Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**RA** 2 g/day PO in divided doses	3 gm/day
Enbrel® (etanercept)	**RA** 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira® (adalimumab)	**RA** 40 mg SC every other week (may increase to once weekly)	40 mg/week
glucocorticoids	**PV, GPA and MPA** 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.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): fatal infusion reactions, severe mucocutaneous reactions, hepatitis B virus reactivation, and progressive multifocal leukoencephalopathy

Appendix D: General Information

- Definition of MTX or Disease-Modifying Antirheumatic Drug (DMARD) failure
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to RA therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living

Appendix E: FDA-Approved and Off-Label NCCN-Recommended Uses for Non-Hodgkin's Lymphoma
The following conditions are subtypes of Non-Hodgkin's Lymphoma approvable per FDA labeling and NCCN 1 or 2A recommendation.

Indication	Rituxan	Rituxan Hycela
Acute lymphoblastic leukemia	N	
AIDS-related B-cell lymphoma	N	N
Burkitt lymphoma	N	N
Castleman's disease	N	N
CLL/SLL	F	F
DLBCL	F	F
FL	F	F
Hairy cell leukemia	N	
Mantle cell lymphoma	N	N
Gastric MALT lymphoma	N	N
Nongastric MALT lymphoma	N	N
Splenic marginal zone lymphoma	N	N
Nodal marginal zone lymphoma	F	
Primary cutaneous B-cell lymphoma	N	N
Post-transplant lymphoproliferative disorder	N	N
Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma	N	

F = FDA indication; N = NCCN category 1 or 2A off-label use

V. Dosage and Administration

Drug Nam	Indication	Dosing Regimen	Maximum Dose
Rituxan	NHL	375 mg/m^2 IV infusion according to the following schedules: Relapsed or Refractory, Low-Grade or Follicular, CD20-Positive, B-Cell NHL: once weekly for 4 or 8 doses Retreatment for Relapsed or Refractory, Low-Grade or Follicular, CD20-Positive, B-Cell NHL: once weekly for 4 doses Previously Untreated, Follicular, CD20-Positive, B-Cell NHL: administer on Day 1 of each cycle of chemotherapy, for up to 8 doses; In patients with complete or partial response, initiate Rituxan maintenance eight weeks following completion of Rituxan in combination with chemotherapy. Administer Rituxan as a single-agent every 8 weeks for 12 doses. Non-progressing, Low-Grade, CD20-Positive, B-Cell NHL, after first-line CVP [cyclophosphamide, vincristine, prednisone] chemotherapy: following completion of 6-8 cycles of CVP chemotherapy, administer once weekly for 4 doses at 6-month intervals to a maximum of 16 doses Diffuse Large B-Cell NHL: administer on Day 1 of each cycle of chemotherapy for up to 8 doses total As a component of Zevalin® for NHL: 250 mg/m^2 IV within 4 hrs prior to administration of Indium-111-(In-111-) Zevalin and Yttrium-90-(Y-90) Zevalin. Administer rituximab and In-111-Zevalin 7–9 days prior to rituximab and Y-90-Zevalin.	375 mg/m^2 IV infusion according to the above schedules

Drug Nam	Indication	Dosing Regimen	Maximum Dose
		Doses may vary for chemotherapy regimens and are based on body surface area. Refer to oncology literature.	
	CLL	375 mg/m^2 IV infusion on the day prior to initiation of chemotherapy with fludarabine and cyclophosphamide chemotherapy, then 500 mg/m^2 on Day 1 of cycles 2-6 (every 28 days)	500 mg/m^2/day
	RA	Two-1000 mg IV infusions separated by 2 weeks (i.e., day 1 and day 15), followed by two-1000 mg IV infusions every 16 weeks. Rituxan is given in combination with MTX.	1000 mg/week
	GPA/MPA	375 mg/m^2 IV once weekly for 4 weeks in combination with glucocorticoids	375 mg/m^2/week
	PV	Two-1000 mg IV infusions separated by 2 weeks with a tapering course of glucocorticoids, then 500 mg IV at month 12 and every 6 months thereafter or based on clinical evaluation For relapse: 1000 mg IV once, then resume maintenance dose 16 weeks later	Initial/relapse: 1000 mg/dose Maintenance: 500 mg/6 months
Rituxan Hycela	FL	First dose must be with IV rituximab 1,400 mg rituximab and 23,400 units hyaluronidase SC according to the following schedules: Relapsed or Refractory, Follicular Lymphoma: once weekly for 3 or 7 weeks (i.e., 4 or 8 weeks in total) Retreatment for Relapsed or Refractory, Follicular Lymphoma: once weekly for 3 weeks (i.e., 4 weeks in total) Previously Untreated, Follicular Lymphoma: Administer on Day 1 of Cycles 2–8 of chemotherapy (every 21 days), for up to 7 cycles (i.e., up to 8 cycles in total). In patients with complete or partial response, initiate maintenance treatment 8 weeks following completion of Rituxan Hycela in combination	1,400 mg/23,400 units SC per injection

Drug Nam	Indication	Dosing Regimen	Maximum Dose
		with chemotherapy. Administer as a single-agent every 8 weeks for 12 doses. Non-progressing, Follicular Lymphoma after first line CVP chemotherapy: Following completion of 6–8 cycles of CVP chemotherapy and a full dose of a rituximab product by intravenous infusion at week 1, administer once weekly for 3 weeks (i.e., 4 weeks in total) at 6 month intervals to a maximum of 16 doses	
	DLBCL	First dose must be with IV rituximab 1,400 mg rituximab and 23,400 units hyaluronidase SC on Day 1 of Cycles 2–8 of CHOP chemotherapy for up to 7 cycles (i.e., up to 6–8 cycles in total)	1,400 mg/23,400 units SC per injection
	CLL	First dose must be with IV rituximab 1,600 mg/26,800 units on Day 1 of Cycles 2–6 (every 28 days) for a total of 5 cycles (i.e., 6 cycles in total)	1,600 mg/26,800 units SC per injection

VI. Product Availability

Drug Name	Availability
Rituximab (Rituxan)	Single-use vials for IV injection: 100 mg/10 mL, 500 mg/50 mL
Rituximab/hyaluronidase (Rituxan Hycela)	Single-dose vials for SC injection: 1,400 mg/23,400 units, 1,600 mg/26,800 units

VII. References

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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
J9310	Injection, rituximab, 100 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.86.Arthritis Treatments. All Indications: Criteria related to HBV, malignant disease, concomitant use with other biologics, and concurrent administration of live vaccines removed from contraindications. Added dosing. Changed contraindication/discontinuation reason from "active infection, including localized infection" to "active, serious infection." RA: changed age requirement to 18; added requirement for trial and failure of PDL Enbrel and Humira, unless contraindicated; if the former are contraindicated, to require trial of methotrexate; if the former is contraindicated, added sulfasalazine as an alternative. In addition to RA, all other FDA-approved indications are added as well as NCCN compendia uses. Re-auth: combined into All Indications; added dosing and reasons to discontinue. Approval durations are 3 and 6 months for oncology and 6 and 12 months for all other indications.	06.16	07.16
Added ICD-10 code table	10.16	
CP.PHAR.148.Rituximab Oncology Hematology policy is incorporated into the present policy (criteria, codes). NHL: The FDA CLL labeled indication is added under NHL. Nodal marginal zone lymphoma is added under NCCN uses. Maximum dose is added. Safety information is removed. Duration is increased to 6 months. RA: modified the RA diagnostic criteria from requiring one or more of the following: ≥ 5 inflamed joints, elevation in the erythrocyte sedimentation rate (ESR) and/or serum C-reactive protein (CRP) concentration; positive rheumatoid factor and/or anticyclic citrullinated peptide (CCP) antibodies (present in most patients), evidence of inflammation on plain radiography of the hands, wrists, or feet, such as osteopenia and/or periarticular swelling to the ACR diagnostic criteria. Safety information is removed. Autoimmune hemolytic anemia (from policy 148): Warm and cold agglutinin disease are combined into one criteria set and edited to	07.17	07.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
reflect rituximab as first-line for cold agglutinin disease and post glucocorticoids for warm agglutinin disease. ICD-10 CM code table updated per NCCN compendia: added C79.32, D36.0, Z85.71, Z85.72, Z85.79		
2Q 2018 annual review: added HIM line of business; summarized NCCN and FDA approved uses for improved clarity for Non-Hodgkin's Lymphoma; added specialist involvement in care into one criteria set; removed diagnosis requirement for ACR criteria in RA; revised conventional DMARD requirement in RA to require at least one conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine); off-label criteria added for additional NCCN-recommended diagnoses; removed off-label criteria for autoimmune hemolytic anemia and immune thrombocytopenia, will instead defer to off-label policy; approval durations updated; references reviewed and updated.	02.27.18	05.18
Criteria added for new indication for Rituxan: pemphigus vulgaris; myasthenia gravis and nephrotic syndrome diagnoses added to policy as covered diagnoses if off-label criteria is met; references reviewed and updated.	7.31.18	11.18

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.