Rituximab hyaluronidase human (Rituxan Hycela®)

Place of Service
Office Administration
Infusion Center Administration
Outpatient Facility Administration
Home Infusion

HCPCS: **J9311** per 10 mg

Condition(s) listed in policy (*see criteria for details*)

- B-cell mediated cancers – *See separate coverage criteria for CLL, SLL, DLBCL, follicular lymphoma, and Waldenstrom macroglobulinemia / lymphoplasmacytic lymphoma in their own sections*
- Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)
- Diffuse large B-cell lymphoma (DLBCL)
- Follicular lymphoma
  - Previously untreated
  - Non-progressing (including stable disease)
  - Relapsed or refractory
- Waldenstrom macroglobulinemia / lymphoplasmacytic lymphoma

AHFS therapeutic class: Antineoplastic agent
Mechanism of action: Anti-CD20 monoclonal antibody

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Rituxan Hycela™ (rituximab hyaluronidase human) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

B-cell mediated cancers

1. Diagnosis of B-cell lymphoma *(e.g., AIDS-related B-cell lymphomas, Burkitt, Castleman's disease, Diffuse large B-cell, Follicular lymphoma, Gastric MALT lymphoma, High-grade B-cell lymphomas, Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma, Mantle cell lymphoma, Nodal marginal zone lymphoma, Nongastric MALT lymphoma, Post-transplant lymphoproliferative disorders, Primary cutaneous B-cell lymphoma, Splenic marginal zone lymphoma)*, **AND**
2. Receiving intravenous form of rituximab as first dose on Day 1 of Cycle 1, **AND**
3. Intolerable side effect with preferred rituximab products (Truxima, Ruxience and Riabni) that is not expected with Rituxan Hycela, or contraindication to preferred rituximab products (Truxima, Ruxience and Riabni) for ongoing use.

Covered Doses

Initial Therapy or Retreatment of active disease:

Following rituximab IV dose: up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) per dose for up to 7 SC doses per treatment course

Maintenance Therapy is covered for only the following subtypes:

Must be a diagnosis of one of the following:

- Marginal zone (MZL)
- Mantle cell (MCL)
- Post-transplant lymphoproliferative disorders (PTLD)

For MZL, and PTLD patients who are considered in remission, cover maintenance treatment: *Following initial rituximab IV dose,* cover up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) per dose for up to 7 SC doses for the first year. Up to 8 SC doses allowed for the second year.

For MCL patients who are considered in remission, cover maintenance treatment: *Following initial rituximab IV dose,* cover up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) per dose for up to 7 SC doses for the first year. Up to 8 SC doses allowed for subsequent years.

Coverage Period
Initial and Retreatment of active disease:
Cover for 7 SC doses per treatment course (initial dose should be Rituxan IV)

Maintenance for patients considered in remission:
FL, MZL, PTLD: Cover yearly for up to 2 years (15 SC doses total, initial dose should be IV Rituxan)
MCL: Cover yearly (initial dose should be IV Rituxan)
ICD-10:
B20, C82.00-C82.09, C82.60-C82.69, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99, C83.00-C83.09, C83.10-C83.19, C83.30-C83.39, C83.70-C83.79, C83.80-C83.89, C83.90-C83.99, C85.20-C85.29, C85.80-C85.89, C88.4, D36.0, D47.Z, D47.Z2, R59.0, R59.1, R59.9, Z85.72

Chronic lymphocytic leukemia and small lymphocytic lymphoma

1. Receiving intravenous form of rituximab as first dose on Day 1 of Cycle 1, **AND**
2. Intolerable side effect with preferred rituximab products (Truxima, Ruxience and Riabni) that is not expected with Rituxan Hycela, or contraindication to preferred rituximab products (Truxima, Ruxience and Riabni) for ongoing use.

Covered Doses
Following rituximab IV dose on Day 1 of Cycle 1:
Up to 1,400 mg/26,800 units (rituximab/hyaluronidase human) SC for up to 15 doses, OR
Up to 1,600 mg/26,800 units (rituximab/hyaluronidase human) SC for up to 8 doses

Coverage Period
Up to 375 mg/m2 for 15 doses, or up to 500 mg/m2 for 8 doses

ICD-10:
C83.00-C83.09, C91.10, C91.12

Diffuse large B-cell lymphoma, previously untreated

1. Being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens, **AND**
2. Receiving intravenous form of rituximab as first dose on Day 1 of Cycle 1, **AND**
3. Intolerable side effect with preferred rituximab products (Truxima, Ruxience and Riabni) that is not expected with Rituxan Hycela, or contraindication to preferred rituximab products (Truxima, Ruxience and Riabni) for ongoing use.

Covered Doses
Following rituximab IV dose on Day 1 of Cycle 1: up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) SC on Day 1 of Cycles 2 through 8 for a total of 7 cycles. Cycle length dependent upon chemotherapy regimen being used.

Coverage Period
7 cycles

ICD-10:
C83.30-C83.39, Z85.72

Follicular lymphoma, previously untreated

1. Being initiated in combination with first-line chemotherapy, **AND**
2. Receiving intravenous form of rituximab as first dose on Day 1 of Cycle 1, **AND**
3. Intolerable side effect with preferred rituximab products (Truxima, Ruxience and Riabni) that is not expected with Rituxan Hycela, or contraindication to preferred rituximab products (Truxima, Ruxience and Riabni) for ongoing use.

Covered Doses
Following rituximab IV dose on Day 1 of Cycle 1: up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) SC on Day 1 of Cycles 2 through 8 (every 21 days) for a total of 7 cycles.
As single agent maintenance treatment in patients achieving a complete or partial response to Rituxan Hycela in combination with chemotherapy: up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) SC every 8 weeks for 12 doses, starting 8 weeks following completion of Rituxan Hycela in combination with chemotherapy

Coverage Period
Initial coverage in combination with chemotherapy: Seven 21-day cycles

Single agent maintenance in patients achieving a complete or partial response to Rituxan Hycela in combination with chemotherapy: 12 doses administered 8 weeks apart, starting 8 weeks following completion of Rituxan Hycela in combination with chemotherapy

ICD-10:
C82.00-C82.09, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99, C83.00-C83.09

Follicular lymphoma, non-progressing (including stable disease)

1. Being used as a single agent after 6 to 8 cycles of first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy, **AND**
2. Receiving intravenous form of rituximab as first dose at week 1, **AND**
3. Intolerable side effect with preferred rituximab products (Truxima, Ruxience and Riabni) that is not expected with Rituxan Hycela, or contraindication to preferred rituximab products (Truxima, Ruxience and Riabni) for ongoing use.

Covered Doses
Following rituximab IV dose at week 1: up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) SC once weekly for 3 weeks (for first 4 weeks) followed by once weekly for 4 weeks

administered six months later and at 6-month intervals thereafter, up to a maximum of 16 doses.

Coverage Period
Yearly up to 2 years
ICD-10:
C82.00-C82.09, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99, C83.00-C83.09

Follicular lymphoma, relapsed or refractory

1. Being used as single agent, **AND**
2. Receiving intravenous form of rituximab as first dose in week 1, **AND**
3. Intolerable side effect with preferred rituximab products (Truxima, Ruxience and Riabni) that is not expected with Rituxan Hycela, or contraindication to preferred rituximab products (Truxima, Ruxience and Riabni) for ongoing use.

Covered Doses
Following rituximab IV dose in week 1: up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) SC once weekly for up to 7 weeks

Coverage Period
7 weeks
ICD-10:
C82.00-C82.09, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99, C83.00-C83.09

Waldenstrom macroglobulinemia / lymphoplasmacytic lymphoma

1. Receiving IV form of rituximab as first dose in week 1, **AND**
2. Intolerable side effect with preferred rituximab products (Ruxience and Riabni) that is not expected with Rituxan Hycela, or contraindication to preferred rituximab products for ongoing use, **AND**
3. Intolerable side effect with preferred rituximab products (Truxima, Ruxience and Riabni) that is not expected with Rituxan Hycela, or contraindication to preferred rituximab products (Truxima, Ruxience and Riabni) for ongoing use.

Covered Doses
Treatment of active disease:
Following rituximab IV dose: Up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) SC for up to 12 doses per treatment course

Maintenance therapy:
Up to 1,400 mg/23,400u (rituximab/ hyaluronidase human) SC up to 8 doses per year

Coverage Period
Treatment of active disease:
Cover up to 12 doses per treatment course

Maintenance therapy:
Cover up to 8 doses per year

ICD-10:
C88.0

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Rituxan Hycela™ (rituximab hyaluronidase human) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medical necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 1,400 mg/23,400 units (rituximab/hyaluronidase human) per 11.7 mL (single-dose vial)
- 1,600 mg/26,800 units (rituximab/hyaluronidase human) per 13.4 mL (single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Rituxan Hycela (2021). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. B-Cell Lymphomas (Version 4.2021). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 1.2022). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Primary Cutaneous Lymphomas (Version 2.2021). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma (Version 2.2022). Available at http://www.nccn.org.
- Rituxan Hycela® (rituximab hyaluronidase human) [Prescribing information]. South San Francisco, CA: Genentech; 6/2021.

(7) Policy Update

Date of last review: 1Q2022
Date of next review: 1Q2023
Changes from previous policy version:

- New indication in Section (2): Added coverage for Waldenstrom macroglobulinemia / lymphoplasmacytic lymphoma
  Rationale: NCCN category 2A support

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee