

JURISDICTION SPECIFIC MEDICARE PART B

WINRHO SDF (Rho[D] Immune Globulin Intravenous [Human])

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. The FDA-labeled indications uses are listed below:

- A. Immune thrombocytopenia purpura (ITP) in non-splenectomized Rho(D)-positive
 - 1. Children with chronic or acute ITP
 - 2. Adults with chronic ITP
 - 3. Children and adults with ITP secondary to HIV infection
- B. Suppression of Rh isoimmunization in non-sensitized Rho(D)-negative patients with an Rh-incompatible pregnancy, including:
 - 1. Routine antepartum and postpartum Rh prophylaxis
 - 2. Rh prophylaxis in cases of:
 - i. Obstetric complication (e.g., miscarriage, abortion, threatened abortion, ectopic pregnancy or hydatidiform mole, transplacental hemorrhage resulting from antepartum hemorrhage)
 - ii. Invasive procedures during pregnancy (e.g., amniocentesis, chorionic biopsy) or obstetric manipulative procedures (e.g., external version, abdominal trauma)
- C. Suppression of Rh isoimmunization in Rho(D)-negative individuals transfused with Rho(D)-positive red blood cells (RBCs) or blood components containing Rho(D)-positive RBCs.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available in a legible format with patient identification information (e.g., complete name and dates of service) and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

- A. The information contained in the medical record should include all relevant diagnostic laboratory studies, prior history of bleeding, infection, disease progression, prior medical/surgical therapies and any other information essential in establishing that the patient meets the coverage indicators set forth in the NCD and LCD.

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- B. An accurate weight in kilograms should be documented prior to the infusion since the dosage is based on mg/kg dosage.
- C. Indications for administration of immune globulin must be fully documented in the patient's medical record.

Physicians or other providers filing Medicare claims for administration of immune globulin therapy at the request of another provider assume full responsibility as to the medical necessity for immune globulin under terms and conditions of NCD and LCD. These providers must also be able to meet documentation requirements given above, either directly through their own medical records or indirectly through records obtained from the referring physician.

III. CRITERIA FOR APPROVAL

- A. **Treatment of Idiopathic Thrombocytopenic Purpura (ITP)**
Authorization of 12 months may be granted for treatment of idiopathic thrombocytopenic purpura in a Rho (D)-positive patient.
- B. **Rh-Incompatible Pregnancy**
Authorization of 12 months may be granted for treatment of preventing antepartum and postpartum Rhesus immunization including in cases of obstetric complication and invasive procedures during pregnancy.
- C. **Suppression of Rhesus Isoimmunization from Blood Products**
Authorization of 1 month may be granted for suppression of Rh isoimmunization in Rho(D)-negative individuals transfused with Rho(D)-positive red blood cell or blood components containing Rho(D)-positive red blood cells.

IV. REFERENCES

1. Intravenous Immune Globulin (IVIG) LCD (L35093) Version R20. Available at: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=35093&ver=100&bc=CAAAAAAAAAA>. Accessed June 29, 2021.
2. Billing and Coding: Intravenous Immune Globulin (IVIG) (A56786) Version R4. Available at: <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=56786&ver=18&keyword=billing%20and%20coding&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAAA&KeywordLookUp=Doc&KeywordSearchType=Exact> Accessed June 29, 2021.
3. WinRho [package insert]. Roswell, GA: Saol Therapeutics, Inc.; July 2019.