FIRST COAST SERVICE OPTIONS
MAC - PART A/B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L34019

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 - Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Rho (D) Immune Globulin Intravenous

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

Transmittal 1261 (Change Request 5635, dated 06/01/2007)
Rho (D) Immune Globulin Intravenous

**Primary Geographic Jurisdiction**

Florida
Puerto Rico/Virgin Islands

**Oversight Region**

Region I

**Original Determination Effective Date**

10/01/2015

**Original Determination Ending Date**

N/A

**Revision Effective Date**

N/A

**Revision Ending Date**

N/A

**Indications and Limitations of Coverage and/or Medical Necessity**

Rho (D) Immune Globulin Intravenous (Rho [D] IGIV) is a gamma globulin (IgG) which contains antibodies to Rho (D). Rho (D) IGIV currently has two medical applications. The first application is to suppress Rh isoimmunization in nonsensitized Rho (D) antigen-negative individuals following Rho (D) antigen-positive red blood cell or whole blood exposure. Rho (D) antigen-positive red blood cell exposure or whole blood exposure can occur by fetomaternal hemorrhage during delivery of a Rho (D) antigen-positive infant, during an abortion (spontaneous or induced), during amniocentesis, abdominal trauma or during a mismatched transfusion (transfusion accident).

The second application of Rho (D) IGIV is to increase platelets in non-splenectomized, Rho (D) positive children with acute or chronic immune thrombocytopenic purpura (ITP) and adults with chronic ITP, or ITP secondary to human immunodeficiency virus (HIV) infection.

Rho (D) Immune Globulin Intravenous will be considered medically necessary for the following Food and Drug Administration (FDA) approved indications:

1.) For the suppression of Rh isoimmunization. These include:
   A.) Rho (D) negative female children and adults in their childbearing years upon exposure to Rho (D) positive transfusions or massive fetal hemorrhage.
   B.) Non-sensitized Rho (D) negative women within 72 hours after abortions (spontaneous or induced), amniocentesis, chorionic villus sampling, ruptured tubal pregnancy, abdominal trauma, transplacental hemorrhage, or in the normal course of pregnancy unless the blood type of the fetus or the father is known to be Rho (D) negative. Maternal bleeding due to threatened abortion should be treated by administration of Rho (D) as soon as possible.
   C.) Non-sensitized Rho (D) negative women during pregnancy at 28 weeks gestation and within 72 hours following delivery which meet the following criteria:

   - The mother must be Rho (D) negative;
   - The mother is carrying a child whose father is either Rho (D) positive or Rho (D) unknown;
   - The baby is either Rho (D) positive or Rho (D) unknown, and isoimmunized to the Rho (D) factor.
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- Abdominal trauma
- Mismatched blood transfusion (Transfusion accident).

For the treatment of pregnancy and other obstetrical concerns, Rho (D) can be administered intramuscularly or intravenously as follows:

- 1500 IU should be administered at twenty-eight (28) weeks gestation. If administered earlier in pregnancy, it is recommended by the manufacturer that administration should be at twelve (12) week intervals.
- 600 IU should be administered as soon as possible after delivery of a confirmed Rho (D) positive baby and no later than 72 hours. If more than 72 hours have elapsed, Rho (D) should be administered as soon as possible up to twenty-eight (28) days after delivery.
- 600 IU should be administered immediately after abortion, amniocentesis (after 34 weeks gestation) or any other manipulation late in pregnancy (after 34 weeks gestation) associated with increased risk of Rh isoimmunization. Administration should take place within 72 hours after the event.
- 300 IU should be administered immediately after amniocentesis before 34 weeks gestation or after chorionic villus sampling. This dose should be repeated every 12 weeks while woman is pregnant. In case of threatened abortion, Rho (D) should be administered immediately.

For the treatment of massive fetal hemorrhage or incompatible blood transfusion, Rho (D) should be administered within 72 hours after exposure utilizing the following formulas:

- If exposed to Rho (D) positive whole blood, administer 90 IU/mL blood IM or 45 IU/mL blood IV.
- If exposed to Rho (D) positive red blood cells, administer 60 IU/mL IM or 120 IU/mL IV.
- Administer 3000 IU every 8 hours via the IV route until total dosage calculated is administered.
- Administer 6000 IU every 12 hours via the intramuscular route until total dose calculated is administered.

2.) For the treatment of ITP for non-splenectomized Rho (D) positive individuals in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in:

- Children with acute or chronic ITP;
- Adults with chronic ITP;

For the purpose of this policy, ITP is defined by the following criteria:

- Signs and symptoms of bleeding, a platelet count of less than 30,000/mm3, Rho (D) positive status and non-splenectomized status;
- Acute ITP: for duration of less than 6 months.
- Chronic ITP: for duration of greater than 6 months.

3. For the treatment of non-splenectomized Rho (D) positive children and adults with immune thrombocytopenic purpura (ITP) secondary to HIV who meet the following criteria:

- Platelet count below 30,000 with signs and symptoms of bleeding and undergoing antiretroviral therapy or
- Individuals with a platelet count below 30,000 who are receiving anti-retroviral therapy and are undergoing a surgical or extensive dental procedure. Treatment may be initiated prior to the procedure. This is a prophylactic procedure and it is not expected that treatment with Rho (D) will continue after the procedure.

Initial Dose

For the treatment of ITP, Rho (D) must be given by intravenous administration.

- An initial dose of 250 IU/Kg body weight, given as a single injections, is recommended. The initial dosage can be administered in two divided doses given on separate days.
- If the patient has a Hgb level that is less than 10g/dL, a reduced dose of 125 to 200 IU/Kg should be given to minimize the risk of increasing the severity of anemia in the patient.
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Subsequent Dosing

- If subsequent therapy is required to elevate platelet counts to > 30,000 and the clinical condition calls for a higher platelet count, an intravenous dose of 125 to 300 IU/Kg body weight of Rho (D) is recommended.

Maintenance Therapy

- After the first two infusions, clinically indicated repeat doses would not be expected sooner than 3-4 weeks.
- Dosing 125-300 IU/Kg individualized based on platelet and Hgb levels.
- If patient does not respond to initial dose, administer a subsequent dose based on Hgb:
  - Hgb between 8-10 g/dL, re-dose between 125-200 IU/Kg
  - Hgb > 10 g/dL, re-dose between 250-300 IU/Kg
  - Hgb > 8 g/dL, use with caution

All patients should be monitored to determine clinical response by assessing platelet counts, red blood cell counts, hemoglobin (Hgb) and other indices as necessary. The average interval is every three weeks but may be more frequent dependent upon the clinical condition of the patient. Initially, complete blood counts (CBC) should be performed at least weekly and prior to every dose of Rho (D) but then can be done less often. However the CBC should always be performed prior to the administration of Rho (D).

Type of Bill Code

Hospital – 13x
Skilled Nursing Facility – 23x
Critical Access Hospital – 85x

Revenue Codes

636 Drugs Requiring Detailed Coding

CPT/HCPCS Codes

- J2788 Injection, Rho D immune globulin, human, minidose, 50 micrograms (250 IU)
- J2790 Injection, Rho D immune globulin, human, full dose, 300 micrograms (1500 IU)
- J2791 Injection, Rho D immune globulin, human, (Rhophylac), intramuscular or intravenous, 100 IU
- J2792 Injection, Rho D immune globulin, intravenous, human, solvent detergent, 100 IU

ICD-10 Codes that Support Medical Necessity

- D47.3 Essential (hemorrhagic) thrombocytopenia
- D69.3-D69.49 Purpura and other hemorrhagic conditions
- O36.0110-O36.0139 Maternal care for anti-D [Rh] antibodies
- O36.0190-O36.0199 Maternal care for anti-D [Rh] antibodies, unspecified trimester
- O36.0910-O36.0939 Maternal care for other rhesus isoimmunization
- O36.0990-O36.0999 Maternal care for other rhesus isoimmunization, unspecified trimester
- P55.0 Rh isoimmunization of newborn
- T80.40XA-T80.49XS Rh incompatibility reaction due to transfusion of blood or blood products
- T80.A0XA-T80.A9XS Non-ABO incompatibility reaction due to transfusion of blood or blood product,

Diagnoses that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity
Rho (D) Immune Globulin Intravenous

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Associated Information

Documentation Requirements

Medical record documentation (e.g. history and physical, office/progress notes) maintained by the performing physician must clearly indicate the medical necessity to initiate Rho (D) Immune Globulin therapy. Medical record documentation should demonstrate continued need for the administration of Rho (D). Documentation must clearly indicate relevant signs and symptoms related to the condition for which this therapy is indicated. If product recommended dosages are exceeded, the provider must document medical necessity in the medical record.

Documentation supporting the use of Rho D in patients with HIV/AIDS and severe thrombocytopenia must include Rh-positive status, all relevant platelet counts, clinical history of bleeding signs or symptoms, and notes of a surgical or extensive dental procedure if applicable. Also, status of current antiretroviral therapy must be outlined. If the physician providing the Rho (D) infusion incident to his/her evaluation and management is not the prescribing physician of antiretroviral therapy, the physician must verify in the medical record as to why Rho (D) therapy is being prescribed outside adjustment and management of antiretroviral therapy. This should occur rarely and the evaluation that initiates the Rho (D) therapy for medical necessity will be reviewed. The entire episode of care of Rho (D) infusion will be denied if the initiating evaluation does not meet medical necessity.

Utilization Guidelines

N/A

Sources of Information and Basis for Decision

FCSO reference LCD number(s) – L29012, L29270, L29387


Gaines, Reed (2000). Acute onset hemoglobinemia and/or hemoglobinuria and sequelae following Rho (D) immune globulin intravenous administration in immune thrombocytopenic purpura patients. This reference was used to review the result of laboratory values after the administration of Rho (D).

McCrae, K., Bussel, J., Pier, M.M., et al (2001). Platelets: An Update on Diagnosis and Management of Thrombocytopenic Disorders. Abstract. This reference was used to review the treatment of thrombocytopenic disorders.


WinRho SDF™ package insert, 2002. This reference used to obtain manufacturer recommended doses.
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**Start Date of Comment Period**
N/A

**End Date of Comment Period**
N/A

**Start Date of Notice Period**
04/01/2014

**Original**
Publication: April 2014 Connection

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

**Related Documents**
N/A

**LCD Attachments**

Coding Guidelines

Document formatted: 07/16/2013(DA/et)