

# Minnesota Models Law for Hospital 'Never Events'

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Private payers are watching with interest to see how Medicare implements its new policy of withholding payment for certain hospital-acquired conditions and infections.

But Minnesota is already leading the way in this area. In 2003, the state began requiring hospitals to report on 27 so-called "never events" identified at that

time by the National Quality Forum (NQF). The NQF list of such adverse events, defined as mistakes that should never occur in the hospital, includes wrong-site surgeries, objects left during surgery, and serious medication errors.

Under the Minnesota reporting law, hospitals must report these never events, investigate the underlying cause, and take corrective action.

In September, Gov. Tim Pawlenty (R) announced the next step. Hospitals in the

state have agreed not to bill insurance companies or patients for any of the 27 events identified by the NQF.

"It seems obvious to us, but Minnesota is the first state in the nation to agree that patients, employers, and insurers shouldn't pay for care made necessary by an adverse health event," Gov. Pawlenty said in a statement. "We hope more states will follow our lead."

The plan, which was created by the Minnesota Hospital Association and the

Minnesota Council of Health Plans, is similar to a program launched in 2005 by HealthPartners Inc., a Minnesota-based health care insurer.

Building on the earlier quality-reporting efforts within the state, HealthPartners not only stopped paying hospitals for charges associated with never events, it also prohibited hospitals from billing the plan's members.

The program has become a national model, according to Babette Aplan, senior vice president for health and care management at HealthPartners. Officials from the plan have consulted with the Leapfrog Group and the Medicare Payment Advisory Commission.

Although there was some controversy around the HealthPartners policy when it was first implemented, hospitals quickly got on board, Ms. Aplan said.

Because never events are rare, the savings to the health plan for withholding payment has been negligible, Ms. Aplan said. Instead, the program's aim was to provide hospitals with an incentive to systematically prevent these events. ■

## Rh<sub>0</sub>(D) Immune Globulin (Human)

**RhoGAM® Ultra-Filtered PLUS (300 µg) (1500 IU)**

**MICRhoGAM® Ultra-Filtered PLUS (50 µg) (250 IU)**

### Rx Only

#### For Intramuscular Injection Only

Prefilled syringes, preservative-free (thimerosal free), latex-free delivery system

#### INDICATIONS AND USAGE

##### Pregnancy and other obstetrical conditions

For administration to Rh-negative women not previously sensitized to the Rh<sub>0</sub>(D) factor, unless the father or baby are conclusively Rh-negative.

- Delivery of an Rh-positive baby irrespective of the ABO groups of the mother and baby
- Antepartum prophylaxis at 26 to 28 weeks gestation
- Antepartum fetal-maternal hemorrhage (suspected or proven) as a result of placenta previa, amniocentesis, chorionic villus sampling, percutaneous umbilical blood sampling, other obstetrical manipulative procedure (e.g., version) or abdominal trauma
- Actual or threatened pregnancy loss at any stage of gestation
- Ectopic pregnancy

To maintain an adequate level of anti-D, RhoGAM should be administered every 12 weeks. If delivery of the baby does not occur 12 weeks after the administration of the standard antepartum dose (at 26 to 28 weeks), a second dose is recommended to maximize protection antepartum.

##### Transfusion of Rh-incompatible blood or blood products

- Prevention of Rh immunization in any Rh-negative person after incompatible transfusion of Rh-positive blood or blood products (e.g., red blood cells, platelet concentrates, granulocyte concentrates)

#### CONTRAINDICATIONS

- The use of RhoGAM and MICRhoGAM is contraindicated in Rh-positive individuals.

#### DOSAGE AND ADMINISTRATION

For intramuscular use only, do not administer intravenously.

##### Pregnancy and other obstetrical conditions

- RhoGAM (300 µg) (1500 IU)
- Postpartum — if the newborn is Rh-positive. Administer within 72 hours of delivery.
- Antepartum —
  - Prophylaxis at 26–28 weeks gestation.
  - At or beyond thirteen weeks gestation: administer within 72 hours when suspected or proven exposure to Rh-positive red blood cells occurs resulting from invasive procedures, abdominal trauma or obstetrical manipulation, ectopic pregnancy, pregnancy termination or threatened termination.

Administer every 12 weeks starting from first injection to maintain a level of passively acquired anti-D. If delivery occurs within three weeks after the last antepartum dose, the postpartum dose may be withheld, but a test for fetal-maternal hemorrhage should be performed to determine if exposure to >15 mL of red blood cells has occurred.

##### MICRhoGAM (50 µg) (250 IU)

- Administer within 72 hours of actual or threatened termination of pregnancy (spontaneous or induced) up to and including 12 weeks gestation.

##### Transfusion of Rh-incompatible blood or blood products

Administer within 72 hours.

- RhoGAM (300 µg) (1500 IU)
- 2.5–15.0 mL Rh-positive red blood cells
- >15.0 mL Rh-positive red blood cells (multiple syringes)

##### MICRhoGAM (50 µg) (250 IU)

- <2.5 mL Rh-positive red blood cells

#### WARNINGS AND PRECAUTIONS

##### Warnings

- For intramuscular use only, do not inject intravenously.
- In the case of postpartum use, the product is intended for maternal administration.
- Do not inject the newborn infant.
- Patients should be observed for at least 20 minutes after administration.
- Administer with caution to patients who have had prior severe systemic allergic reactions to human immune globulin.
- RhoGAM / MICRhoGAM contain a small quantity of IgA. There is a potential risk of hypersensitivity in IgA deficient individuals.
- Patients treated for Rh-incompatible transfusion should be monitored by clinical and laboratory means for signs and symptoms of a hemolytic reaction.
- Store at 2 to 8°C. Do not store frozen.
- Do not use after the expiration date printed on the syringe.

Parenteral drug products should be inspected visually for particulate matter, discoloration and syringe damage prior to administration. Do not use if particulate matter and / or discoloration are observed. The solution should appear clear or slightly opalescent.

#### Use of Plasma Derived Products

RhoGAM and MICRhoGAM are made from human plasma and may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically the Creutzfeldt-Jakob disease (CJD) agent. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing plasma for the presence of certain current virus infections and by using pathogen removal and inactivation techniques during the manufacturing process. All of the above steps are designed to increase product safety by reducing the risk of pathogen transmission.

Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. All infections thought by a physician possibly to have been transmitted by these products should be reported by the physician or other healthcare provider in the United States to Ortho-Clinical Diagnostics, Inc. at 1-800-421-3311. Outside the United States, the company distributing these products should be contacted. The physician should discuss the risks and benefits of these products with the patient.

#### ADVERSE REACTIONS

Adverse events (AE) after administration of RhoGAM and MICRhoGAM are rare.

The most frequently reported AEs are anti-D formation and injection site reactions, such as swelling, induration, redness and mild pain or warmth. Possible systemic reactions are skin rash, body aches or a slight elevation in temperature. Severe systemic allergic reactions are extremely rare. Patients should be observed for at least 20 minutes after administration. There have been no reported fatalities due to anaphylaxis or any other cause related to RhoGAM or MICRhoGAM administration.

As with any Rh<sub>0</sub>(D) Immune Globulin (Human), administration to patients who are Rh-positive or have received Rh-positive red blood cells may result in signs and symptoms of a hemolytic reaction, including fever, back pain, nausea and vomiting, hypo- or hypertension, hemoglobinuria/emia, elevated bilirubin and creatinine and decreased haptoglobin.

RhoGAM and MICRhoGAM contain a small quantity of IgA (less than 15 µg per dose). Although high doses of intravenous immune globulin containing IgA at levels of 270–720 mg/mL have been given without incident during treatment of patients with high-titered antibodies to IgA, the attending physician must weigh the benefit against the potential risks of hypersensitivity reactions.

#### DRUG INTERACTIONS

Immune globulin preparations including Rh<sub>0</sub>(D) Immune Globulin (Human) may impair the efficacy of live vaccines such as measles, mumps and varicella. Administration of live vaccines should generally be delayed until 12 weeks after the final dose of immune globulin. If an immune globulin is administered within 14 days after administration of a live vaccine, the immune response to the vaccination may be inhibited.

Because of the importance of rubella immunity among women of childbearing age, the postpartum vaccination of rubella-susceptible women with rubella or MMR vaccine should not be delayed because of the receipt of Rh<sub>0</sub>(D) Immune Globulin (Human) during the last trimester of pregnancy or at delivery. Vaccination should occur immediately after delivery and if possible, testing should be performed after 3 or more months to ensure immunity to rubella and if necessary, to measles.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy Category C

Animal reproduction studies have not been conducted with RhoGAM or MICRhoGAM. The available evidence suggests that Rh<sub>0</sub>(D) Immune Globulin (Human) does not harm the fetus or affect future pregnancies or the reproduction capacity of the maternal recipient.

##### Rh Blood Type

RhoGAM or MICRhoGAM Rh<sub>0</sub>(D) Immune Globulin (Human) should only be administered to Rh-negative patients exposed or potentially exposed to Rh-positive red blood cells to prevent Rh immunization.

#### OVERDOSAGE

Repeated administration or increased dosage in Rh-negative individuals should not cause more severe or more frequent adverse reactions than the normal dose. Patients who receive RhoGAM or MICRhoGAM for Rh-incompatible transfusion should be monitored by clinical and laboratory means due to the risk of a hemolytic reaction.

#### DESCRIPTION

RhoGAM and MICRhoGAM Rh<sub>0</sub>(D) Immune Globulin (Human) are sterile solutions containing immunoglobulin G (IgG) anti-D (anti-Rh) for use in preventing Rh immunization. They are manufactured from human plasma containing anti-D. A single dose of RhoGAM contains sufficient anti-D (300 µg or 1500 IU) to suppress the immune response to up to 15 mL of Rh-positive red blood cells. A single dose of MICRhoGAM contains sufficient anti-D (50 µg or 250 IU) to suppress the immune response to up to 2.5 mL of Rh-positive red blood cells.

The final product contains 5 ± 1% IgG, 2.9 mg/mL sodium chloride, 0.01% Polysorbate 80 (non-animal derived) and 15 mg/mL glycine. Small amounts of IgA, typically less than 15 µg per dose, are present. The pH range is 6.20–6.55 and IgG purity is ≥ 98%. The product contains no added human serum albumin (HSA), no thimerosal or other preservatives and utilizes a latex-free delivery system.

#### CLINICAL PHARMACOLOGY

RhoGAM and MICRhoGAM act by suppressing the immune response of Rh-negative individuals to Rh-positive red blood cells. The mechanism of action is unknown. RhoGAM, MICRhoGAM and other Rh<sub>0</sub>(D) Immune Globulin (Human) products are not effective in altering the course or consequences of Rh immunization once it has occurred.

NOTE: For complete prescribing information, see package insert.

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