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RETHYMIC (allogeneic processed thymus tissue–agdc)

ICD-10-PCS PRESENTATION

March 8, 2022

MED-US-802-2200001

What is RETHYMIC?

RETHYMIC® is indicated for immune reconstitution in pediatric patients with congenital athymia.

RETHYMIC is engineered human thymus tissue designed to reconstitute the thymic function that children with congenital athymia are missing. RETHYMIC does not require donor-recipient matching.

Patients with congenital athymia are born without a thymus, a condition causing profound immunodeficiency, life-threatening immune dysregulation, and high susceptibility to potentially fatal infections.

Without treatment, congenital athymia is fatal in childhood. In a natural history population observed from 1991 through 2017, 49 patients diagnosed with congenital athymia received supportive care only. The 2-year survival rate was 6%, with all patients dying by 3 years of age.

RETHYMIC was granted FDA approval on October 8, 2021.

What does RETHYMIC do?

RETHYMIC is engineered human thymus tissue designed to reconstitute the immune system in pediatric patients with congenital athymia and is administered as a one-time regenerative tissue-based therapy for immune reconstitution in pediatric patients.

The mechanism of action involves the migration of recipient T cell progenitors from the bone marrow to the implanted RETHYMIC slices, where they develop into naïve immunocompetent recipient T cells.

Evidence of thymic function can be observed with the development of naïve T cells in the peripheral blood; this is unlikely to be observed prior to 6-12 months after treatment with RETHYMIC.

How is RETHYMIC used?

RETHYMIC is indicated for immune reconstitution in pediatric patients with congenital athymia.

RETHYMIC is not indicated for the treatment of patients with severe combined immunodeficiency (SCID).

RETHYMIC is allogeneic processed thymus tissue that is administered via surgical implantation into the quadriceps muscle.

What is the Route of Administration for RETHMIC?

RETHYMIC is allogenic processed thymus tissue with varying thickness and shape that is implanted during a surgical procedure.

The route of administration is implantation into the furrows of the quadriceps muscle via open surgical procedure.

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Procedural Steps to Administering RETHYMIC

RETHYMIC is administered via surgical implantation by a qualified surgical team in a single surgical session at a qualified hospital.

RETHYMIC is implanted as an open surgical procedure, between the furrows of the quadriceps muscle, in accordance with the prescribing information.

Implantation of RETHYMIC into the quadriceps requires a healthy bed of muscle tissue.

Immunosuppressive therapy is recommended for patients receiving RETHYMIC based on disease phenotype and PHA levels.

Procedural Steps to Administering RETHYMIC continued

After induction of general anesthesia, a cranial-caudal skin incision should be made over the anterior thigh compartment.

The fascia is opened to expose the quadriceps muscle. Pockets are created in between the muscle fibers. Each pocket should be made along the natural furrows throughout the quadriceps muscle group.

Individual RETHYMIC slices should be implanted into the pockets between the muscle fibers in the quadriceps muscle.

Once each RETHYMIC slice has been implanted, it should be fully covered by muscle tissue and a single absorbable suture should be used to close the pocket where the RETHYMIC slice was implanted.

Once the intended dose has been implanted, close the skin incision with 2 layers of absorbable sutures and apply a standard dressing, such as wound closure strips or skin glue. Leave the fascia open to allow room for muscle compartment swelling. An occlusive dressing may be used to prevent contamination.

RETHYMIC Utilization by Setting

RETHYMIC will be administered to the appropriate patients only in the hospital inpatient setting.

Setting for utilization is determined by the clinical presentation of the patient and the need for sterile isolation.

Diagnostic Codes to Report Administering RETHYMIC

The ICD-10-CM code to report RETHYMIC is D82.1 for Di George's syndrome.

There are no other ICD-10-CM coding options that apply to congenital athymia.

Where is the Use of RETHYMIC Reported in a Medical Record?

The administration of RETHYMIC would be reported in the body of the procedure report with details on dose and route of administration.

Medical coders will determine the appropriate ICD-10-PCS code from the name of the drug administered, based on the descriptor assigned the new code.

What are the Different Naming Conventions for RETHYMIC?

The generic name for this drug is Allogeneic processed thymus tissue–agdc.

The drug trade name is RETHYMIC.

Possible Complications for RETHYMIC

Immune reconstitution sufficient to protect from infection is unlikely to develop prior to 6 to 12 months after treatment with RETHYMIC. Given the immunocompromised condition of athymic patients, infection control measures should be followed until the development of thymic function can be established.

Monitor and treat patients at risk for the development of graft versus host disease.

Monitor for the development of autoimmune disorders

Pre-existing renal impairment is a risk factor for death.

Pre-existing cytomegalovirus infection may result in death prior to the development of thymic function.

Monitor for the development of lymphoproliferative disorder (blood cancer).

Transmission of infectious diseases may occur because RETHYMIC is derived from human tissue.

Immunizations should not be administered in patients who have received RETHYMIC until immune-function criteria have been met.

Patients should be tested for anti-HLA antibodies prior to treatment.

Most Common Adverse Events (> 10%) related to RETHYMIC in Clinical Trials

The most common (>10%) adverse events related to RETHYMIC included:

- Hypertension (high blood pressure, 19%)
- Cytokine release syndrome (18%), rash (15%)
- Hypomagnesemia (low magnesium, 16%)
- Renal impairment / failure (decrease of kidney function, 12%)
- Thrombocytopenia (low platelets, 12%)
- Graft versus host disease, (10%)

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Thank you for your consideration


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