Medical Policy

Paternal or Fetal Immunotherapy for Recurrent Fetal Loss

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Policy Number: 387
BCBSA Reference Number: 4.02.02

Related Policies
- Oncologic Applications of Photodynamic Therapy, Including Barrett's Esophagus, #454

Policy
Commercial Members: Managed Care (HMO and POS), PPO, Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members
Paternal or fetal antigen immunotherapy using seminal plasma, trophoblast membrane, or paternal leukocytes is NOT MEDICALLY NECESSARY.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
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<th>Outpatient</th>
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<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<td>Commercial PPO and Indemnity</td>
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<td>Medicare HMO BlueSM</td>
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<td>Medicare PPO BlueSM</td>
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CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
CPT Codes
There is no specific CPT code for this service.

Description
Recurrent pregnancy loss (RPL), or recurrent spontaneous abortion, is a term conventionally applied when a clinically recognized pregnancy spontaneously terminates before 20 weeks gestation in two or more consecutive pregnancies with the same partner. It must be recognized that recurrent pregnancy loss differs from sporadic pregnancy loss, which may occur throughout the reproductive years.

A number of factors have been identified as contributory to RPL. Most common are anatomic defects such as structural uterine abnormalities, uterine fibroids, and endometrial polyps. Cervical incompetence may also present. A less common cause may be chromosomal abnormalities such as translocations, inversions, and recurrent aneuploidy. Hormonal causes of RPL are known as "luteal phase defects" and may be the result of inadequate progesterone effect on the endometrial lining.

Less well understood as possible mechanisms in recurrent pregnancy loss are disorders of the immune mechanism. The two subclasses of the immunologic response are autoimmunity, whereby the female's immune system "attacks" her own tissues, and alloimmunity, in which the fetus may be perceived by the mother's immune system as a "foreign" tissue. A number of diagnostic approaches have been proposed, and some interventions have been developed in an attempt to modulate the immune response and improve the chances of survival of the fetus.

Paternal or fetal antigen immunotherapy involves the artificial stimulation of the protective maternal immune response using biological preparations containing paternal or fetal antigens to help prevent recurrent fetal loss where no detectable cause can be identified. Three techniques have been used:
- Seminal plasma: Seminal plasmas and blood specimens from normal donors are capsulated and administered as vaginal suppositories on days 7, 14, and 21 of the monthly cycle and continued twice weekly after the first missed menses until 30 weeks into pregnancy.
- Trophoblast membrane: Extracts are prepared from placentas collected at delivery from healthy term pregnancies. Villous tissue is separated from other placental components. The sieved solution is centrifuged. Membrane pellets are resuspended in sterile, pyrogen-free saline, then UV-irradiated, washed, re-homogenized, and lyophilized for storage. Membrane pellets are then reconstituted and administered with saline.
- Paternal leukocytes: Paternal whole blood is subjected to density gradient centrifugation. Mononuclear leukocytes are removed from the gradient, washed, and resuspended in normal saline. Patients are immunized with the paternal leukocytes and then encouraged to conceive within a short time frame.

Summary
A MEDLINE search did not identify any randomized controlled trials published on this therapy. Therefore, this treatment is considered investigational.

In general, research interest in immunotherapy as a treatment of recurrent spontaneous abortion has focused on the use of intravenous immunoglobulin. This therapy is considered separately in policy 310.

Policy History
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No changes to policy statements.

No changes to policy statements.

No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References