blue of california

Medical Policy

Orthopedic Applications of Stem Cell Therapy	
Type: Investigational / Experimental	**Policy Specific Section:** Medicine
Original Policy Date: March 29, 2013	**Effective Date:** March 29, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Mesenchymal stem cells (MSCs) have the capability to differentiate into a variety of tissue types, including various musculoskeletal tissues. Potential uses of MSCs for orthopedic applications include treatment of damaged bone, cartilage, ligaments, tendons and intervertebral discs.

Policy

Mesenchymal stem-cell therapy is considered **investigational** for all orthopedic applications, including use in repair or regeneration of musculoskeletal tissue.

Policy Guideline

Note: There are currently no products using engineered mesenchymal stem cells (MSCs) that have been approved by the FDA for orthopedic applications. The FDA has determined that the MSCs sold by Regenerative Sciences for use in the Regenexx™ procedure would be considered drugs or biological products and thus required submission of a New Drug Application (NDA) or Biologics Licensing Application (BLA) to the FDA. At the time of this policy development (2013), no NDA or BLA has been approved by the FDA for this product.

Coding

- There are no specific codes for orthopedic applications of stem cell therapy.
- The appropriate CPT code for reporting this procedure is 20999, or the code for an unlisted procedure of the body area on which the procedure is performed.
- In addition, CPT codes 38206, 28230, 38232 are used for the harvesting of MSC for transplantation, and CPT code 38421 may be used for actual MSC transplantation.

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review
• No records required

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the appendix for this policy

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