Stem cell therapy & exosomes

Separate scientific promise, approved products, and investigational claims.

THE KEY POINT

The exact product and the exact medical use matter. The phrase 'stem cell' is not proof that a treatment is effective, approved or appropriate.

Understand the words

Stem cells can make more cells of their own kind and develop into specialized cells. Their capabilities differ. PRP, bone marrow concentrate, manufactured cell products and exosomes are different preparations. Laboratory potential does not establish a benefit for your diagnosis. [21]

Some cell therapies are approved

FDA has approved specific cell therapies for specific uses. Ryoncil has a defined pediatric graft-versus-host disease indication. MACI is a cultured cartilage-cell implant for specified knee cartilage defects. Neither approval validates a generic 'stem-cell shot' for arthritis, hair loss or anti-aging. [10-12]

What about exosomes?

FDA's consumer alert states there are no FDA-approved exosome products. Ask about current status using the FDA product list, not a clinic's marketing label. This guide does not recommend exosome treatment. [10,23]

Education only. Individual care requires a qualified clinician. Clinical review pending.

Evidence, benefits & tradeoffs

A current safety message

FDA's 2026 patient warning highlights potential serious harm from unapproved human cell or tissue products. An August 2026 warning letter also identifies unapproved products and manufacturing concerns. [13,14]

Registration is not approval

An establishment registration or a ClinicalTrials.gov listing does not prove that a product is legally marketed, safe or effective. Ask for the specific approval or investigational details. [9,22]

Promising is not proven

A treatment should be judged by human clinical evidence for the proposed product, dose, route and diagnosis, with clear discussion of uncertainty and alternatives.

RISKS TO DISCUSS

Risks described by FDA for unapproved regenerative products include serious infections, unwanted inflammatory or immune responses, unwanted tissue growth and treatment failure. A product made from your own cells is not automatically risk-free. [9]

Compare the alternatives

Before considering an investigational procedure, review established treatments and whether a legitimate clinical trial is relevant. Ask about independent oversight, written consent, costs and who handles adverse events. [9,22]

Education only. Individual care requires a qualified clinician. Clinical review pending.

Make the conversation count

1. What is the exact product name, source and manufacturer?
2. What is the product's regulatory status, and what authorization or rules apply to the proposed use?
3. Can I see the product's official indication or trial documents?
4. Which human studies support this product for my diagnosis?
5. What safety testing, oversight and follow-up apply?
6. What established options should I compare before deciding?

Why evaluation matters

If you have persistent symptoms, seek a diagnosis and discuss established options. A sales deadline is not a medical reason to accept an investigational treatment. You can ask questions and obtain a second opinion.

The RegenLuma approach

RegenLuma's commitment is to make distinctions visible: approved versus investigational, potential versus demonstrated benefit, and education versus an individualized treatment recommendation.

Education only. Individual care requires a qualified clinician. Clinical review pending.

Sources & your notes

Read the original resources for context. These sources support education; they do not endorse RegenLuma or determine your eligibility for treatment.

[9] U.S. Food and Drug Administration: Patient information about regenerative medicine therapies (June 3, 2021; interpret with current approvals)

[10] U.S. Food and Drug Administration: Approved cellular and gene therapy products (Current FDA product list)

[11] U.S. Food and Drug Administration: Ryoncil approval for a specific pediatric graft-versus-host disease indication (December 18, 2024)

[12] U.S. Food and Drug Administration: MACI: cultured cartilage cells for specified knee cartilage defects (FDA product information)

[13] U.S. Food and Drug Administration: 2026 warning about unapproved human cell or tissue products (FDA 2026 patient warning; checked October 21, 2026)

[14] U.S. Food and Drug Administration: R3 Medical Companies warning letter (August 14, 2026)

[21] National Institutes of Health: Stem Cell Basics (Current science education resource)

[22] National Library of Medicine: Understanding what a ClinicalTrials.gov listing means (January 23, 2018)

[23] U.S. Food and Drug Administration: Consumer alert: stem cells and exosomes (July 22, 2020; cross-checked with current FDA information)

Notes for my visit