VITA NOVA
STEM CELL PROFESSIONALS

FAMILY EDUCATION GUIDE

REGENERATIVE MEDICINE AND AUTISM

How umbilical cord-derived mesenchymal stem cells (MSCs), Dezawa Muse Cells, exosomes, and secretomes are being studied for autism-related symptoms: what research suggests, what it does not yet show, and questions worth asking.

UC-MSCs | DEZAWA MUSE CELLS | EXOSOMES | SECRETOMES



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INVESTIGATIONAL THERAPIES · EDUCATIONAL INFORMATION ONLY · NOT A CURE

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A NOTE TO FAMILIES

If you are reading this guide, you are likely looking for every possible way to support someone you love. Regenerative medicine for autism receives a great deal of attention online, and it can be hard to separate careful science from hype. This guide explains the science in plain language, shares what three published studies actually report, and is honest about what is still unknown.

> **PLEASE KEEP IN MIND**
>
> The therapies described here are **investigational** for autism. They are not a cure, results are not guaranteed, and they are not a replacement for the behavioral, educational, developmental, and medical care your child or family member already receives.

WHAT IS AUTISM?

Autism spectrum disorder (ASD) refers to a group of complex neurodevelopmental conditions that typically appear before age three. It is marked by challenges in social interaction, in communication (both verbal and nonverbal), and by repetitive or restricted behaviors [1]. Autism is truly a spectrum: some individuals function independently, while others need extensive support [1]. As reported in a 2026 review, the U.S. Centers for Disease Control and Prevention (CDC) estimated in 2023 that about 2.76% of 8-year-olds in the U.S. are diagnosed with ASD [1].

WHAT CAUSES AUTISM?

Researchers link autism to a combination of genetic, epigenetic, environmental, and immune-related factors that affect brain structure and function [1]. How these factors interact, and the exact brain mechanisms involved, are still not completely understood [2].

> **WHY RESEARCHERS ARE LOOKING AT INFLAMMATION**
>
> Disruptions in how brain cells communicate (synaptic function), activation of the brain's resident immune cells (microglia), and inflammatory signaling molecules (cytokines) have all been implicated in autism, and may play different roles in different individuals [2]. One common hypothesis is that inflammation or immune activation may disrupt typical brain development [2]. Many regenerative approaches are studied for their effects on inflammation, which is one reason they have drawn research interest.

TODAY'S STANDARD CARE

Current treatments primarily involve behavioral, educational, and sometimes medication-based approaches aimed at reducing symptoms and improving daily functioning [1]. Medications may address specific issues such as anxiety or hyperactivity, but they do not target autism's core features, and researchers have called for new treatment strategies to be studied [1].

REGENERATIVE OPTIONS EXPLAINED

"Regenerative medicine" is a broad term. The four approaches below are related but different. A simple way to think about them: two are **cells** (MSCs and Dezawa Muse Cells), and two are the **messages cells send** (exosomes and the broader secretome).

THE KEY IDEA: CELLS AS MESSENGERS

In autism, researchers generally consider it unlikely that donor cells become new brain cells. Instead, the leading idea is that cells release signals, called paracrine effects, that may help support tissue repair and maintenance [2].

MSCs

Umbilical cord-derived

MSCs are a varied group of cells that research shows can be isolated from bone marrow, fat (adipose) tissue, and birth tissues such as umbilical cord blood, cord tissue, and placenta [2]. The MSCs offered at Vita Nova are umbilical cord-derived (UC-MSCs). The main effects of MSCs are thought to come from the signals they release, including calming immune activity, supporting blood-vessel growth, and helping protect cells [2]. MSCs have relatively low immunogenicity, so donor cells can be used without the tissue matching other transplants require [2]. In autism, researchers hypothesize MSCs may help modulate inflammation and quiet overactive microglia, though laboratory evidence for these mechanisms is still limited [2].

DEZAWA MUSE CELLS

Multilineage-differentiating Stress-Enduring cells

Dezawa Muse Cells are stem cells that arise naturally in tissues such as bone marrow, adipose tissue, amnion, and umbilical cord, rather than being created by genetic reprogramming. The Dezawa Muse Cells described by their manufacturer come from umbilical cord tissue, where they are identified as the SSEA-3-positive subset of mesenchymal stromal cells. According to the manufacturer, they can self-renew and generate cell types of all three germ layers, stay relatively quiet until activated by tissue injury, and may home to damaged sites, while their growth remains tightly controlled. **Evidence in autism is limited. See page 5.**

EXOSOMES

Extracellular vesicles (EVs)

Exosomes are tiny, membrane-wrapped packages released by cells, part of a larger family called extracellular vesicles (EVs). They carry proteins, microRNAs, messenger RNAs, and other molecules cells use to communicate [1]. Because they are not living cells, EVs are considered a "cell-free" approach; researchers note they may offer greater stability, lower immunogenicity, and a reduced risk of immune rejection compared with whole cells [1]. Research on MSC-derived EVs for autism has so far been done in animal models [1].

SECRETOMES

Everything a cell releases

The secretome is the full set of substances a cell releases: vesicles such as exosomes plus many dissolved (soluble) factors, such as signaling proteins. In research, secretome products are often prepared as "conditioned medium," the liquid cells were grown in, which is more complex and less well-defined than purified EVs [1]. Only one of the six animal studies in the reviewed meta-analysis used conditioned medium, and it was not analyzed separately [1]. **Evidence specific to secretome therapy for autism is very limited.**

WHAT THE RESEARCH SHOWS

STUDIES IN CHILDREN AND ADULTS WITH AUTISM

As of May 2020, 15 studies of cell therapies in autism were registered on ClinicalTrials.gov in seven countries. All were early-stage (phase 1 or 2) studies, mostly single-arm and open-label, using umbilical cord blood, MSCs, or the person's own bone marrow [2]. Results were available for seven of them:

Published registered clinical trials of cell therapies in autism, as summarized in [2]

Study	Design	Country	Participants	Ages (yrs)	Cell source	Route
Lv et al.	Nonrandomized	China	37	3–12	Donor cord blood cells ± cord MSCs	IV and intrathecal
Sharma et al.	Single arm, open label	India	32	3–33	Own bone marrow MSCs	Intrathecal
Riordan et al.	Single arm, open label	Panama	20	6–15	Donor umbilical cord MSCs	IV
Chez et al.	Randomized controlled	US	29	2–6	Own cord blood	IV
Dawson et al.	Single arm, open label	US	25	2–5	Own cord blood	IV
Dawson et al.	Randomized controlled	US	180	2–7	Own or donor cord blood	IV
Sun et al.	Single arm, open label	US	12	4–9	Donor umbilical cord MSCs	IV

IV = intravenous. Intrathecal = into the spinal fluid. Source labels simplified from the original table (autologous = own; allogeneic = donor).

WHAT THESE STUDIES SUGGEST

- **Single-arm studies** suggest cell products can be given to children with autism with relative safety, and they generally report improvement on some measures of autism symptoms in at least a portion of participants. Without a comparison group, however, those gains cannot be attributed to the cells themselves [2].
- **In one randomized study**, children received cord blood cells (n=14), cord blood cells plus intrathecal cord tissue MSCs (n=9), or standard therapy (n=14). At 6 months, the combination group showed greater improvement on the Childhood Autism Rating Scale than the other groups, and both treated groups improved more than the comparison group on the Clinical Global Impression scale [2].
- **In a larger randomized study** of 180 children aged 2 to 7, there was no difference between cord blood and placebo groups as a whole in social communication or autism symptoms. Children without intellectual disability who received cord blood showed improved communication skills, increased sustained attention on eye-tracking tests, and increased alpha and beta brain-wave power on EEG [2]. Placebo-group improvement was greater than expected, a reminder of how hard these trials are to run [2].

LABORATORY AND ANIMAL RESEARCH

Much of this research is still at the laboratory and animal stage, and results in animals may not translate to people.

EXOSOMES AND EVS IN ANIMAL MODELS OF AUTISM

A 2026 systematic review and meta-analysis pooled six preclinical studies (published 2018–2024) that gave MSC-derived EVs, mostly exosomes, to mouse models of autism. Five of the six delivered them through the nose (intranasally) [1]. Compared with untreated autism-model mice, treated mice showed [1]:

Pooled results in mice from [1]

Outcome measured in mice	Direction of change	Effect size, SMD (95% CI)	Certainty of evidence
Sociability (three-chamber social test)	Improved	1.34 (0.68 to 2.00)	Low
Repetitive behaviors (self-grooming, rearing)	Reduced	−1.12 (−1.59 to −0.65)	Low
Pro-inflammatory cytokines (IL-6, TNF-α, IL-1β)	Reduced	−1.39 (−2.03 to −0.76)	Very low
Anti-inflammatory cytokine IL-10	Increased	0.58 (0.03 to 1.13)	Low

SMD (standardized mean difference) is a way to combine studies that used different measurements; values farther from zero mean bigger differences between treated and untreated mice. Certainty ratings are the authors' own (GRADE approach).

WHAT THE AUTHORS CAUTION

The authors describe this as preliminary evidence. The number of studies was small, methods varied, some publication bias was possible, and certainty ranged from low to very low. Mouse models do not capture the full diversity of human autism, and the findings "should not be interpreted as direct evidence of clinical efficacy" [1].

DEZAWA MUSE CELLS: HOW GROWTH CONTROL IS DESCRIBED

The manufacturer's brief explains why Dezawa Muse Cells, despite pluripotent-like abilities, are described as having low tumor-forming potential compared with embryonic stem cells and iPSCs:

- **Natural origin.** They arise in normal tissues rather than through artificial genetic reprogramming.
- **"Low-gear" growth.** Low telomerase activity and slower division, more like adult (somatic) stem cells than embryonic stem cells.
- **Intact quality control.** Preserved DNA-damage checkpoints and p53 surveillance, so damaged cells pause, repair, or are eliminated.
- **A molecular "brake."** High let-7 microRNAs and no detectable LIN28, described as restraining the PI3K–AKT growth pathway while pluripotency genes (OCT4, SOX2, NANOG) stay on.

This manufacturer brief is not peer-reviewed and does not list its underlying studies. It describes cell biology and animal-model findings, not results in people or in autism.

SAFETY AND WHAT TO EXPECT

WHAT THE STUDIES REPORT ABOUT SAFETY

- A 2021 review described the safety profile of reported cell therapies in children with neurodevelopmental disorders as **encouraging** [2].
- That review summarized a 2012 analysis of 36 MSC clinical trials with over 1,000 recipients across many conditions: MSC treatment was not associated with acute infusion-related toxicity, organ complications, infection, death, or cancer during up to 5 years of follow-up. The only associated side effect was temporary fever [2].
- The 2026 meta-analysis cites a separate review of 11 clinical trials including 437 patients with autism, in which MSC treatments were well tolerated with no serious adverse events reported [1].

QUESTIONS TO ASK AT YOUR CONSULTATION

- What type of product is being considered (MSCs, Dezawa Muse Cells, exosomes, or secretome), and where does it come from?
- What is the regulatory status of this product and procedure?
- Can I see the Certificate of Analysis and chain-of-custody paperwork for my product?
- What are the known risks and side effects, and how will they be monitored?
- Which specific goals or symptoms will we track, and how will progress be measured?
- How will this fit alongside my child's current therapies and other clinicians?

WHAT TO EXPECT AT VITA NOVA

- **A one-on-one consultation.** We review medical history, discuss symptoms and goals, and talk through what matters most to your family.
- **Realistic expectations.** We explain what a care plan involves, what research does and does not show, and whether regenerative therapy may be appropriate. If we don't believe it is right for your situation, we will tell you directly.
- **Transparency.** For UC-MSC therapy, you receive documentation showing cell count and viability. For Dezawa Muse Cells, you receive a copy of the Certificate of Analysis and chain-of-custody paperwork.
- **Coordination.** Regenerative therapy is not a substitute for established autism care. We encourage families to keep their current care team informed.

ABOUT VITA NOVA AND DR. MEHTA



Kate Sherman, PA-C (left) and Hemal Mehta, MD (right)

Vita Nova Stem Cell Professionals is a regenerative medicine practice located in Franklin, Tennessee, part of the greater Nashville area, serving patients throughout Middle Tennessee and beyond. Our practice is built on transparent, evidence-guided care that respects both the science and the individual needs of each patient.

Kate Sherman, PA-C

PHYSICIAN ASSISTANT

Kate is a certified physician assistant who works alongside Dr. Mehta in patient evaluations and care, helping families understand their options at every step.

Hemal Mehta, MD

LEAD PHYSICIAN

Dr. Mehta is a board-certified physician who leads clinical care at Vita Nova, with a patient-centered, evidence-guided approach and a commitment to explaining every option clearly.

CONTACT US

HAVE QUESTIONS?

We are glad to talk with your family, answer questions about the research, and help you decide whether a consultation makes sense.

Kallie Rasmussen
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YOUR NEXT STEPS

1

REACH OUT

Call or email Kallie to ask questions or schedule a complimentary consultation, in-office or by telehealth.

2

GATHER RECORDS

Bring the diagnosis report, recent evaluations, a list of current therapies and medications, and contact details for your child's care team.

3

BRING YOUR QUESTIONS

Use the questions on page 6 as a starting point, and add anything that matters to your family.

MEDICAL DISCLAIMER

This guide is provided for general educational purposes only and does not constitute medical advice, diagnosis, or treatment, and it does not create a provider–patient relationship.

Umbilical cord-derived MSC, Dezawa Muse Cell, exosome, and secretome therapies are investigational for autism spectrum disorder. They are not approved by the U.S. Food and Drug Administration (FDA) to treat autism, and their safety and effectiveness for autism have not been established. These therapies are not a cure for autism, and no particular outcome is promised or guaranteed. Individual responses vary, and some people may experience no benefit.

The research summarized here includes early-phase human studies, animal studies, and laboratory experiments, which may not predict results for any individual. Statements in this guide are limited to what the cited studies report.

Do not stop or change any existing therapy, medication, or educational program without first speaking with your treating clinicians. Always seek the advice of a qualified healthcare provider with any questions about a medical condition. If you think you or your child may have a medical emergency, call 911.

REFERENCES

1. Mohtashami T, Aghayan AH, Masoudi A, Atashi A, Garmabi B, Jamalpoor Z, Khaksari M. Therapeutic potential of mesenchymal stem cell-derived extracellular vesicles as a cell-free approach in autism spectrum disorder: A systematic review and meta-analysis of preclinical studies. Behavioural Brain Research. 2027;516:116478. Available online 19 September 2026. https://doi.org/10.1016/j.bbr.2026.116478

2. Sun JM, Kurtzberg J. Stem cell therapies in cerebral palsy and autism spectrum disorder. Developmental Medicine & Child Neurology. 2021;63:503–510. Published online 4 January 2021. https://doi.org/10.1111/dmcn.14789

MANUFACTURER INFORMATION (NOT PEER-REVIEWED)

MuseCell Innovations® PTE Ltd. Pluripotent Without the Pain: How Dezawa MuseCells® Dodge Tumor Formation. An MCI Scientific Brief. 7 pp. Undated; no named authors. www.musecellinnovations.com

ABOUT THE EVIDENCE IN THIS GUIDE

Numbered citations refer only to the two studies listed above. Reference [1] is a meta-analysis of animal studies; reference [2] is a review of human clinical research. Neither study tested Dezawa Muse Cells or secretome products in people with autism. Information on Dezawa Muse Cells comes from the manufacturer's scientific brief (listed above as manufacturer information; not peer-reviewed) and Vita Nova's patient education materials. It is provided for context and is not presented as findings of the numbered studies.

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