Complete Biologic Modality Map

A clinical reference to eight regenerative modalities

IN BRIEF

This is a side-by-side reference to the eight biologic modalities distributed by Our Biologics.

For each one it sets out what it is in plain language, where it comes from, whether it is taken from the patient or from a donor, what it contains, how it is stored, what it is most studied for, where the evidence is thin, and how it is regulated.

A comparison table and a pre-use checklist for clinicians follow the individual entries.

Regulatory notice

None of the modalities described here are FDA approved drug or biologic products for the indications discussed. Most are regulated as human cellular and tissue-based products (HCT/Ps) under FDA 21 CFR Part 1271, and platelet-rich plasma is regulated as an autologous blood-derived preparation subject to applicable FDA guidance. Regulatory status, evidence quality and clinical indications vary by modality and continue to evolve.

This document does not recommend specific protocols, dosing, injection techniques or treatment decisions, and it does not state or imply that any modality is clinically superior to another except where explicitly supported by cited comparative evidence. Clinicians must independently evaluate current peer-reviewed evidence, applicable regulations, manufacturer product documentation and individual patient suitability before using any biologic product.

The eight modalities

1. Wharton's Jelly / WJ-MSCs

Umbilical cord-derived mesenchymal stem cells

Plain-language definition	Umbilical cord-derived mesenchymal stem cells (MSCs) sourced from the gelatinous connective tissue surrounding the umbilical vessels. Reported to have the highest MSC density of any perinatal tissue source.
Biological source	Human umbilical cord (Wharton's Jelly connective tissue), collected at consenting full-term Caesarean deliveries.
Autologous or allogeneic	Allogeneic (donor-derived).
Contains	Live MSCs, structural matrix components (collagen I, III, V; long-chain hyaluronic acid; chondroitin sulfate; proteoglycans), and a broad paracrine growth-factor and cytokine secretome, reported to include 60 or more factors such as TGF-beta1, VEGF, PDGF-AA and IL-1RA.
Preparation and storage	Available fresh, cryopreserved or lyophilized. Lyophilized forms are shelf-stable at ambient temperature.
Research areas commonly studied	Orthopedics (joint pain, spine, tendon and ligament), neurology, wound healing and aesthetic medicine. A peer-reviewed secretome review (Drobiova et al., 2023) summarizes immunomodulatory and anti-fibrotic mechanisms.[1]
Current evidence limitations	Much of the mechanistic evidence comes from in vitro and preclinical work. Large, high-quality randomized controlled trials in specific human indications remain limited, and clinical evidence quality varies substantially by indication.
Regulatory considerations	Regulated in the United States as an HCT/P under FDA 21 CFR Part 1271, Section 361, when minimally manipulated and intended for homologous use. Not individually FDA approved for specific disease indications. AATB accreditation and donor screening apply to sourcing.

2. Exosomes / Extracellular Vesicles

Acellular nano-scale signaling vesicles

Plain-language definition	Nano-scale lipid-membrane vesicles, approximately 30 to 150 nanometers, secreted by cells and carrying proteins, lipids and RNA including microRNA that modulate the behavior of recipient cells. Acellular, containing no live cells.
Biological source	Typically isolated from the conditioned culture medium of donor mesenchymal stem cells, for example umbilical cord derived. Source cell type varies by manufacturer.
Autologous or allogeneic	Allogeneic, cell-free. No donor cells are transplanted.
Contains	Proteins, lipids and RNA or microRNA cargo enclosed in a lipid bilayer. No live cells or structural matrix.
Preparation and storage	Can be shelf-stable for extended periods when lyophilized, with no live-cell cold-chain requirement in that form.
Research areas commonly studied	Hair restoration, wound healing, dermatology and neurology, where their small size is reported to allow crossing of the blood-brain barrier in preclinical models. A general overview (Di Bella, 2022) summarizes biogenesis, isolation methods and application considerations.[2]
Current evidence limitations	The field is young. Isolation methods, dosing units and potency assays are not yet standardized across manufacturers or studies, which complicates cross-study comparison. Human clinical trial evidence is still emerging relative to cellular therapies.
Regulatory considerations	Regulated as an HCT/P or, depending on manipulation and claims, potentially subject to closer FDA scrutiny as a biologic drug. Regulatory treatment of exosome products continues to evolve and should be independently verified for each specific product and claim.

3. Platelet-Rich Plasma (PRP)

Autologous concentrated platelets from the patient's own blood

Plain-language definition	An autologous concentration of platelets and plasma growth factors, prepared same-day from a patient's own blood by centrifugation.
Biological source	The patient's own peripheral blood, drawn by venipuncture.
Autologous or allogeneic	Autologous. From the patient, for the patient.
Contains	Concentrated platelets and their alpha-granule growth factors such as PDGF, TGF-beta1, VEGF and EGF, plasma proteins, and variable leukocyte content depending on preparation.
Preparation and storage	Prepared fresh, same-day, from freshly drawn blood. Not stored or banked.
Research areas commonly studied	Tendinopathy, knee osteoarthritis, hair restoration and oral and maxillofacial surgery. A 2026 PRISMA-guided methodological review (Berdini et al.) addresses preparation standardization in orthopedic use.[3]
Current evidence limitations	Preparation protocols vary widely across studies and commercial systems in centrifugation speed and time, leukocyte content and activation method. The cited standardization review identifies this as a major barrier to comparing outcomes across the PRP literature.[3]
Regulatory considerations	PRP preparation systems and kits are subject to FDA oversight, and some commercial systems hold 510(k) clearance for specific indications. PRP is not FDA approved as a drug for the indications discussed here.

4. Bone Marrow Aspirate Concentrate (BMAC)

Autologous cells and growth factors from bone marrow

Plain-language definition	An autologous concentrate of mesenchymal stem cells, hematopoietic progenitor cells and growth factors, harvested from the patient's own bone marrow and concentrated by centrifugation.
Biological source	The patient's own bone marrow, most commonly aspirated from the posterior iliac crest.
Autologous or allogeneic	Autologous.
Contains	Live MSCs, hematopoietic progenitor cells and growth factors such as TGF-beta, BMP-2 and IGF-1.
Preparation and storage	Prepared same-day from freshly aspirated bone marrow. Not stored or banked.
Research areas commonly studied	ACL reconstruction augmentation, cartilage repair, spine and knee osteoarthritis. A 2025 meta-analysis of randomized controlled trials (Park et al.) examines BMAC augmentation in ACL reconstruction.[4]
Current evidence limitations	Individual study cohorts are often small. Comparative data against other biologics such as PRP is limited to a small number of studies, and results for structural and functional outcomes are mixed across the literature.
Regulatory considerations	Autologous, minimally manipulated same-day use is generally regulated under Section 361 HCT/P guidelines. BMAC is not FDA approved as a drug for the indications discussed here.

5. Adipose-Derived MSCs (ADSCs)

Mesenchymal stem cells harvested from fat tissue

Plain-language definition	Mesenchymal stem cells harvested from a patient's own subcutaneous adipose tissue by minimally invasive lipoaspirate, reported to offer high MSC yield relative to other adult tissue sources.
Biological source	The patient's own subcutaneous adipose tissue, commonly abdomen, flank or thigh.
Autologous or allogeneic	Autologous, or allogeneic depending on product and jurisdiction. Verify per product.
Contains	Live MSCs with adipogenic, osteogenic and chondrogenic differentiation capacity, plus a paracrine secretome.
Preparation and storage	Processed same-day by enzymatic or mechanical isolation of the stromal vascular fraction. Same-visit injection is used in some protocols.
Research areas commonly studied	Knee osteoarthritis, wound healing and scar revision. A 2023 comparative clinical trial (Pintore et al.) directly compares ADSC and BMAC injections for knee osteoarthritis in 102 patients.[5]
Current evidence limitations	Comparative evidence against other cellular biologics such as BMAC is limited to a small number of head-to-head trials, and long-term structural outcome data is limited.
Regulatory considerations	Autologous, minimally manipulated same-day use is generally regulated under Section 361 HCT/P guidelines. Not FDA approved as a drug for the indications discussed here.

6. Amniotic Membrane

Perinatal tissue with anti-inflammatory and anti-scarring properties

Plain-language definition	Perinatal tissue derived from the innermost layer of the placenta, and in some products amniotic fluid. Used clinically since the early twentieth century, making it among the longest-established biologic tissues in medicine.
Biological source	Human placenta and amniotic sac, collected from consenting donors at healthy full-term deliveries.
Autologous or allogeneic	Allogeneic (donor-derived).
Contains	Structural basement-membrane matrix (collagen IV), growth factors including EGF, bFGF, KGF, TGF-beta and HGF, hyaluronic acid, and anti-inflammatory and anti-microbial proteins.
Preparation and storage	Available fresh, cryopreserved or dehydrated. Dehydrated forms are shelf-stable at room temperature.
Research areas commonly studied	Ophthalmology (corneal surface repair), wound healing, joint pain and oral and maxillofacial surgery. A 2025 systematic review of 9 randomized and prospective studies (Ahmed et al.) examines amniotic membrane transplantation in corneal ulcer healing.[6]
Current evidence limitations	Ophthalmology has the deepest evidence base of any application. Orthopedic and joint-injection uses are comparatively newer and supported by fewer, smaller studies.
Regulatory considerations	Regulated as an HCT/P under FDA 21 CFR Part 1271 where applicable, and manufactured under AATB-accredited, GMP-compliant processes. Not individually FDA approved as a drug for the indications discussed here.

7. Umbilical Cord Blood

Hematopoietic stem cells with an established transplant history

Plain-language definition	Blood collected from the umbilical cord and placenta at birth, containing hematopoietic stem cells with a well-established history of use in hematologic transplantation.
Biological source	Umbilical cord and placental blood, collected at birth and cryo-banked.
Autologous or allogeneic	Allogeneic (donor-derived).
Contains	Hematopoietic stem cells and mononuclear cells. Growth-factor content is comparatively less characterized in the regenerative-medicine literature than in WJ-MSC or PRP products.
Preparation and storage	Cryo-banked at time of collection. Requires cold-chain storage and handling.
Research areas commonly studied	Established use in hematologic disease treatment, with emerging investigational interest in neurological and metabolic applications.
Current evidence limitations	An established evidence base exists for hematologic and transplant indications. Evidence for regenerative-medicine applications outside hematology is comparatively early stage, and current literature should be verified independently for any non-hematologic indication.
Regulatory considerations	Regulated as an HCT/P under FDA 21 CFR Part 1271. Cord blood units used for hematopoietic reconstitution in unrelated recipients may fall under a distinct FDA licensure pathway as a 351 biologic depending on use. The pathway should be confirmed per specific product and intended use.

8. Lyophilized Allografts

Freeze-dried, shelf-stable donor tissue products

Plain-language definition	A processing category rather than a single tissue source. Freeze-dried versions of donor-derived biologic products, for example Wharton's Jelly, exosome or amniotic-derived material, processed to be shelf-stable at ambient temperature.
Biological source	Varies by product. The underlying source is whichever donor tissue was lyophilized, such as umbilical cord or amniotic membrane.
Autologous or allogeneic	Allogeneic (donor-derived), reflecting the source material's origin.
Contains	Varies by underlying source material. Lyophilization is intended to preserve growth-factor activity while removing the need for cold-chain storage.
Preparation and storage	Freeze-dried and shelf-stable at ambient temperature. No cryogenic storage required, which supports point-of-care use.
Research areas commonly studied	Point-of-care logistics research, and shelf-life and bioactivity-retention studies for lyophilized biologic products generally.
Current evidence limitations	Because lyophilized allograft describes a processing method rather than a single biologic, evidence quality and regulatory status should be evaluated for the specific underlying tissue and product, and not assumed to be uniform across all lyophilized products.
Regulatory considerations	Regulatory classification follows the underlying source tissue. Lyophilization itself does not change the applicable HCT/P framework.

Side-by-side comparison

Evidence tier is a general, non-quantitative indicator of relative literature volume and maturity for each modality's most-studied indications. It is not a claim of clinical superiority for any specific condition.

Modality	Source	Auto or allo	Contains	Storage	Evidence tier
Wharton's Jelly / WJ-MSCs	Umbilical cord tissue	Allogeneic	Live MSCs, matrix, growth factors	Fresh, cryo or lyophilized	Growing
Exosomes / EVs	MSC culture medium	Allogeneic	Proteins, lipids, RNA cargo (acellular)	Lyophilized, stable	Emerging
PRP	Patient's own blood	Autologous	Platelets, growth factors	Fresh, same-day	Established
BMAC	Patient's own bone marrow	Autologous	MSCs, progenitors, growth factors	Fresh, same-day	Established (orthopedic)
ADSCs	Patient's own fat tissue	Autologous	Live MSCs, secretome	Fresh, same-day	Growing
Amniotic Membrane	Placenta, amniotic sac	Allogeneic	Matrix, growth factors, anti-inflammatory proteins	Fresh, cryo or dehydrated	Established (ophthalmology)
Umbilical Cord Blood	Cord and placental blood	Allogeneic	Hematopoietic stem cells	Cryo-banked	Established (hematology)
Lyophilized Allografts	Varies by source	Allogeneic	Varies by source	Freeze-dried, shelf-stable	Varies by source

Questions to verify before use

▪ What is the current FDA regulatory classification of this specific product, whether HCT/P Section 361, 351 biologic, or 510(k)-cleared device or system, and does that classification match how the product is being marketed and used?

▪ What peer-reviewed evidence exists for the specific indication being considered, rather than for the modality in general, and what is the quality of that evidence?

▪ For donor-derived products, what is the manufacturer's documentation of donor screening, AATB accreditation, GMP compliance and lot-level sterility testing?

▪ For autologous products, what preparation protocol is being used, and how does it compare with the protocols used in the supporting literature?

▪ Has the patient's suitability been independently assessed against current contraindications and safety considerations for this specific product and indication?

▪ What outcome measures and follow-up plan will be used to evaluate whether the treatment is achieving its intended effect for this patient?

▪ Is the evidence being cited to the patient accurately representing the strength and limitations of the current literature, including where evidence remains preliminary or investigational?

References

[1] Drobiova H, Sindhu S, Ahmad R, Haddad D, Al-Mulla F, Al Madhoun A. Wharton's jelly mesenchymal stem cells: a concise review of their secretome and prospective clinical applications. Front Cell Dev Biol. 2023 Jun 27;11:1211217. DOI 10.3389/fcell.2023.1211217. PMID 37440921. PMCID PMC10333601.

[2] Di Bella MA. Overview and Update on Extracellular Vesicles: Considerations on Exosomes and Their Application in Modern Medicine. Biology (Basel). 2022 May 24;11(6):804. DOI 10.3390/biology11060804. PMID 35741325. PMCID PMC9220244.

[3] Berdini M, Clementi G, Torcianti M, Del Bianco D, Cantori I, Procaccini R, Gigante A. Standardization of Platelet-Rich Plasma Preparation in Orthopedics: A Review of the Literature and Proposal for a Reproducible Protocol. LabMed. 2026;3(1):8. DOI 10.3390/labmed3010008.

[4] Park J, et al. Biological augmentation of ACL reconstruction with BMAC: systematic review and meta-analysis of randomized controlled trials. Int Orthop. 2025 Jan. PMCID PMC11703946.

[5] Pintore A, et al. Intra-articular BMAC versus ADSCs for knee osteoarthritis: prospective comparative clinical trial, 102 patients. J Orthop Surg Res. 2023 May. PMCID PMC10176826.

[6] Ahmed S, et al. Effectiveness of amniotic membrane transplantation in corneal ulcer healing: systematic review of 9 randomized and prospective studies. Cureus. 2025 Jun. PMCID PMC12270348.

[7] American Academy of Orthopaedic Surgeons. Platelet-Rich Plasma (PRP) for Knee Osteoarthritis, Technology Overview. Literature reviewed through August 25, 2021.

[8] Gupta AK, Wang T, Welter R, Unger R, Mejia R. Promises and Pitfalls of Regenerative Therapies for Androgenetic Alopecia. Med Sci (Basel). 2025;14(1):5. DOI 10.3390/medsci14010005. PMCID PMC12821594.

[9] Darwish R, Zakhary M, Wingate K, et al. From Cells to Strands: A Systematic Review Comparing Exosome Therapy, Platelet-Rich Plasma, and Minoxidil for Androgenetic Alopecia Treatment. Cureus. 2025 Jul 14;17(7):e87875. DOI 10.7759/cureus.87875. PMCID PMC12351504.

[10] Tang-Du Hospital. Evaluation of the Therapeutic Effects of Mechanically Engineered Umbilical Cord-Derived Stem Cell Exosomes on Endometrial Injury. ClinicalTrials.gov NCT06896747. Phase 1/2.

[11] Our Biologics modality pages, ourbiologics.com, accessed August 2026: Wharton's Jelly, Exosomes, Platelet-Rich Plasma, Bone Marrow Aspirate, Adipose Derived MSCs, Amniotic Membrane.

Scope note on umbilical cord blood and lyophilized allografts. The descriptive statements for these two categories reflect widely established characteristics of these tissue types in the transplant and regenerative medicine literature. This document makes no efficacy or comparative claim for either category beyond what is stated in their entries above.

This document is provided by Our Biologics for general education. It does not diagnose, treat, cure, or prevent any disease, does not guarantee any individual outcome, and does not recommend a specific protocol, dose, or treatment decision. Clinical decisions

should be made by a qualified provider for each individual patient.