Molina Clinical Policy
Stem Cell Therapy for Orthopedic Applications: Policy No. 426

Last Approval: 12/14/2022
Next Review Due By: December 2023

Ohio Medicaid: All codes that are on the Medicaid Fee schedule will be reviewed for medical necessity and not instantly excluded. This includes 0566T & 0565T for Molina Ohio Medicaid members these are to be reviewed on an individual basis for medical necessity.

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

This policy addresses stem cell therapy for orthopedic applications, specifically mesenchymal stem cells. Stem cell transplantation using hematopoietic stem cells for the treatment of blood cancer, non-cancer conditions, or solid tumors are not addressed in this policy.

Mesenchymal stem cells (MSCs) are non-hematopoietic adult stem cells that originate from mesoderm and are present in bone marrow, fat, synovium, tonsil, peripheral blood, amniotic fluid, umbilical cord blood, and other tissues (Deng et al. 2022). MSCs respond to osteogenic growth stimuli and promote bone repair with their ability to differentiate into resident cells to replace damaged tissues, in addition to possessing potent immunomodulatory properties to regulate surrounding cells and boost tissue repair capacity. These stem cells are capable of self-replication, self-division, self-renewal, and multidirectional differentiation to repair tissues and preserve their homeostasis. MSCs are primarily derived from bone marrow in orthopedics, but other sources include adipose tissue, umbilical cord tissue, amniotic fluid, and other extra-articular sources. Consequently, MSCs have the potential to be used in orthopedic applications, such as the treatment of damaged bone, cartilage, ligaments, tendons, and intervertebral discs, and thus have an important role in tissue regeneration and regenerative medicine (Deng et al. 2022). Stem cell therapy (SCT) for musculoskeletal or orthopedic conditions is an outpatient procedure that begins with patient (autologous) or donor (allogeneic) stem cell collection. Cultured or concentrated cells are then injected into the affected area. MSC therapy has been proposed as a potential treatment for orthopedic conditions, including but not limited to the following:

- Elbow: Injuries, overuse conditions and arthritis (tendon and ligament issues)
- Hand/Wrist: Arthritis and other conditions
- Foot/Ankle: Ligament tears, sprains and instability of the ankle joint, an alternative to fusion or replacement surgery of the ankle
- Hip: Injuries, arthritis, bursitis and other degenerative conditions
- Knee: Arthritis, meniscal tears, tendon and ligament tears, overuse injuries and other conditions
- Shoulder: Arthritis, rotator cuff tears, and other shoulder conditions
- Spine and cervical conditions: Back pain, pain from disc injury or degeneration
- Non-union fractures

The heterogeneity of the SCT treatment protocol, which includes differences in the number of stem cells injected, the use of freshly isolated versus cultured stem cells, the use of additional biomaterial, and the use of stem cells from various sources, makes it difficult to interpret results and reach treatment efficacy conclusions. The lack of large, well-designed randomized controlled trials (RCTs) across all indications, as well as the inconsistency regarding whether SCT has a positive long-term effect, are also significant limitations of SCT.

The peer-reviewed scientific literature on the use of MSCs to promote bone healing lacks sufficient evidence that SCT, alone or in combination with other biomaterials such as an allograft bone product, is effective or consistently improves

health outcomes for any orthopedic indication. This includes degenerative and non-degenerative hip or knee conditions, spinal disc disorders and tendinopathies. Furthermore, no clinical practice guidelines for the use of SCT for any orthopedic condition have been proposed.

Regulatory Status

Autologous stem cell transplantation is a procedure and thus not regulated by the FDA. Medical devices, biologics, drugs, or tests used as part of this procedure may be subject to FDA regulation. Stem cells, similar to other medical products intended to treat, cure, or prevent disease, require FDA approval or clearance prior to marketing. **Currently, regenerative medicine therapies have not been approved for the treatment of any orthopedic condition, such as osteoarthritis, tendonitis, disc disease, tennis elbow, back pain, hip pain, knee pain, neck pain, or shoulder pain** (FDA, 2021).

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, in accordance with the Code of Federal Regulation, Title 21, Sections 1270 and 1271. According to the FDA, "*the only stem cell-based products that are FDA-approved for use in the United States consist of blood-forming stem cells (hematopoietic progenitor cells) derived from cord blood*" and approval is restricted to the treatment of hematopoietic disorders.

Safety concerns of the FDA regarding the use of unproven stem cell therapies include administration site reactions, neurologic conditions, bacterial infection, failure of cells to work as expected, the growth of tumors, and the ability of cells to move from placement sites and change into inappropriate cell types and multiply. According to the FDA statement regarding 'Development of Strategies to Improve Cell Therapy Product Characterization (current as of March 2022):

> *"A major challenge posed by SC therapy is the need to ensure their efficacy and safety. Cells manufactured in large quantities outside their natural environment in the human body can become ineffective or dangerous and produce significant adverse effects, such as tumors, severe immune reactions, or growth of unwanted tissue. In response to this challenge, FDA scientists are developing laboratory techniques that will enable the agency to carefully evaluate and characterize these products in order to reliably predict whether they will be safe and effective.*
>
> *Our laboratories use cell cultures and animal models to develop such techniques and to study the biochemical signals that govern cell behavior during manufacturing and after administration to patients. We are currently using mesenchymal stromal cells, or MSCs, (widely called mesenchymal stem cells) to improve strategies for predicting characteristics of stem-cell based cell products.*
>
> *These studies will help us develop tests that are practical and applicable to specific manufacturing steps."*

No products using engineered or expanded MSCs have been approved by the FDA for orthopedic applications. However, several stem-cell-containing products are available for orthopedic applications:

Orthopedic MSC therapy

- **Regenexx® Stem Cell (Regenexx),** autologous MSCs derived from bone marrow concentrate (BMC), are injected under image guidance to reportedly treat knee, hip, shoulder spine, elbow, hand, wrist, and foot-ankle defects and injuries. Regenexx network facilities in the United States offer Regenexx-SD (Same Day) orthopedic SCT, which harvests and re-injects patients' stem cells on the same day; procedures are not subject to FDA approval. The Regenexx procedures currently available in the U.S. are 1271.15(b) compliant (same surgical procedure) and are not classified as Section 351 drugs by the FDA. The **Regenexx-C Procedure** is only available in the Cayman Islands through an independent vendor who has licensed the procedure. These service providers are not part of nor affiliated with any U.S. Regenexx Network provider. (Regenexx Procedures).

- **Stravix®** (Osiris Therapeutics, Inc.) is a cryopreserved placental tissue, composed of the umbilical amnion and Wharton's Jelly (allogeneic matrix). As a viable wrap for surgical procedures (e.g., tendon repair, Achilles tendon rupture, bunionectomy, hallux rigidus correction, foot amputations, fibromatosis, and arthrodesis), Stravix conforms to injured tissue, can be sutured, and is arthroscopic and robotic procedure friendly. Stravix

is manufactured using a proprietary process allowing the tissue to retain its native components.

The products listed below are examples of commercially available demineralized bone matrix (DBM) products marketed as containing viable stem cells (not an exhaustive list):

Allograft bone products containing viable stem cells

- **AlloStem® Cellular Bone Allograft (AlloSource)** is comprised of adipose derived MSCs with partially demineralized allograft bone.
- **Map3™ (RTI surgical)** contains cortical cancellous bone chips, DBM and multipotent adult progenitor cells.
- **OsteoCel and OsteoCel Plus (Nuvasive®)** is a DBM combined with viable MSCs that have been isolated from allogeneic bone marrow.
- **NuCel® (NuTech Medical):** Derived from amniotic membrane.
- **Trinity Evolution® and Trinity ELITE® (Orthofix®)** is a DBM combined with viable MSCs that have been isolated from allogeneic bone marrow. These cancellous bone allografts contain viable adult MSCs and are intended for the treatment of musculoskeletal defects.

NOTE: The FDA determines the safety and efficacy of a device or medication but does not establish medical necessity; however, FDA approval does not, in and of itself, establish the service, procedure, device or pharmaceutical as medically necessary.

COVERAGE POLICY

Due to the lack of evidence from existing clinical studies and published peer-reviewed literature of improved clinical outcomes, and in the absence of regulatory approval, the use of stem cells in orthopedic applications is considered experimental, investigational, and unproven.

1. MSC therapy (e.g., Regenexx, Stravix) is considered **experimental, investigational, and unproven** for all orthopedic applications. This includes but is not limited to allogeneic or autologous stem cells, harvested bone marrow, adipose tissue, peripheral blood, synovial or amniotic fluid. Examples include:
   - Bone repair or fracture repair (non-union or delayed union)
   - Degenerative conditions
   - Joint disease (e.g., articular cartilage repair, joint capsular injury)
   - Osteonecrosis of the knee and hip
   - Osteoarthritis
   - Chondral / Osteochondral Defect
     - Osteochondritis dissecans of the knee
   - Other knee indications (e.g., pain from ligament or meniscus repair, knee cartilage defects)
   - Regeneration and/or repair of musculoskeletal tissue
   - Spinal disc disorders
   - Tendinopathies

2. Allograft bone products containing viable stem cells, including but not limited to DBM with stem cells (e.g., BIO4, OSTEOCEL Plus, OSTEOCEL Pro, OsteoVive, Trinity Evolution, Trinity ELITE, VIA Form, VIA Graft, ViviGen) are considered **experimental, investigational, and unproven** for all orthopedic applications.

3. Allograft or synthetic bone graft substitutes that must be combined with autologous blood or bone marrow are considered **experimental, investigational, and unproven** for all orthopedic applications.

SUMMARY OF MEDICAL EVIDENCE

MSC Treatment

MSCs are currently being studied for their potential use in a wide range of applications, some of which include but are not limited to the following:

- **Musculoskeletal tissue (muscle, ligament, tendon, and meniscus) regeneration and/or repair** (Chew, et

al., 2017; Lin, et al., 2017; Pas, et al., 2017b; Centeno, et al., 2018a);

- **Joint disease (cartilage lesions, degenerative joint disease, and joint capsular injury) treatment** (Ha, et al., 2019; Park, et al., 2017; Lee, Wang, 2017; Goldberg, et al., 2017);

- **Knee, hip, ankle, and shoulder osteoarthritis** (Natali, et al., 2021; Garza, et al., 2020; Prodromos, et al., 2020; Simunec, et al., 2020; Lee, et al., 2019; Delanois, et al., 2019; Migliorini, et al., 2019; Emadedin, et al., 2018; Jevotovsky, et al., 2018; Centeno, et al., 2018b; Vannabouathong, et al., 2018; Pas, et al., 2017a);

- **Osteonecrosis** (Li, et al., 2021; Andronic et al. 2021)

- **Spinal conditions** such as spinal cord injury and intervertebral disc repair (Khan, et al., 2017).

The published peer-reviewed scientific literature evaluating MSCs for treatment of these conditions consists primarily of preliminary animal studies, case reports, case series, nonrandomized comparative trials, several systematic reviews/meta-analyses, and a few randomized trials. The type/source of stem cell used, and methods of extraction vary across studies. Additionally, sample populations are small, reported outcomes are two years or less in most studies, and injections sometimes include other components such as hyaluronan or platelet rich plasma, making it difficult to attribute the sole effect of MSCs as a treatment response. Therefore, regeneration and tissue remodeling have not been definitively proven in well-designed, controlled trials. Furthermore, the optimal source of MSC, the number of cells to inject, processes for extraction and concentration of MSC, infusion procedures, and indications for use have not been standardized. To establish the safety and efficacy of MSCs utilized for therapy of orthopedic and/or musculoskeletal diseases, additional RCTs investigating long-term outcomes are required since it has not yet been demonstrated that the clinical benefit of MSC treatments outweighs the risk of potential adverse effects.

Most of the systematic reviews identified concluded that the methodology of the studies evaluated was too heterogeneous to allow meaningful conclusions and the bulk of the reviews included or focused entirely on nonrandomized studies, and many included more than one indication. Many trials were not blinded, and randomization methods were debatable, according to reviews that included RCTs. There were also variations in study protocols or treatment approaches, such as the quantity of stem cells injected, the use of autologous versus allogeneic stem cells, the use of freshly isolated versus cultured stem cells, and the use of stem cells from different sources (e.g., bone marrow, adipose tissue, or peripheral blood).-Furthermore, reviews on the same indication included trials with patient cohorts at various stages or severities of illness. Most systematic reviews did not reach definitive conclusions about the efficacy of STC as a treatment for any orthopedic indication, citing the need for larger, higher-quality trials with longer-term follow-up.

An Emergency Care Research Institute (ECRI) report (updated in 2022) for autologous MSC therapy for chronic knee or ankle pain from osteoarthritis indicated that meta-analyses suggest that intra-articular autologous MSC infusions are safe and may reduce chronic pain in knee arthritis; however, pain reduction varies across MSC therapies and pain etiologies; furthermore, the effects are modest, and overall pain relief may not be clinically significant. According to the ECRI, discrepancies in MSC dose, source, processing methods, number of injections, and severity of osteoarthritis prevented them from drawing comparative effectiveness results. In addition, they observed variability in the data, which led to uncertainty regarding the effectiveness of MSC therapy compared to alternative nonsurgical treatments.. ECRI recommended large, multicenter RCTs with standardized methods of MSC preparation, dose, and administration to determine how best to use MSC to treat joint osteoarthritis, as well as additional studies to evaluate MSC therapies in specific patient populations and to compare MSCs with other pharmacologic or biologic therapies, such as hyaluronic acid, growth factors, and non-stem cells (ECRI, 2019; updated January 2022).
Ding et al. (2021) in a systematic review noted the “study is not suitable for making conclusions about which strategy is more advanced in the clinic but is more suitable for making recommendations for the design of further RCTs.” All systematic reviews noted the need for additional high-quality RCTs to determine the appropriate techniques for utilizing autologous or allogeneic MSCs to treat knee osteoarthritis. The number of patients in the RCTs evaluating allogeneic MSC therapy was insufficient to produce reliable results or add to the findings of the systematic reviews.

Cook and Young (2020), in an evidence-based peer review, stated that MSCs remain an investigational therapy for tendon and muscle injuries, as additional research with randomized trials is needed to determine whether MSCs are an effective treatment for tendinopathy, as well as the optimal MSC-harvesting source and the number of MSCs to inject (UpToDate 2022).

A comparative effectiveness review of SCT for joint pain (Hayes, 2022). A total of 16 controlled trials (14 RCT and 2 nonrandomized trials) assessed SCT for joint pain caused by knee osteoarthritis, cartilage injury, knee rheumatoid arthritis, meniscal injury, knee osteonecrosis, rotator cuff injury, and lumbar disc disease. However, these studies involved treatment for 8 different indications in total, and there was either limited evidence or inconsistencies in the results obtained for all these indications. Furthermore, for the two best-studied indications SCT protocols were divergent (e.g., stem cells were obtained from different sources), and there were differences in the surgeries and other treatments that accompanied SCT. None of the studies that met the inclusion criteria looked at patients with hip joint pain. The duration of the follow-up ranged from 3 months to 12 years. The evidence for SCT in adult patients undergoing rotator cuff repair, spinal disc disorders, and osteoarthritis other than knee osteoarthritis was poor and did not support improved outcomes. Complications associated with STC were generally mild and easily managed in the studies reviewed, and included injection site or joint pain, infection, joint warmth, joint swelling, effusions, difficulty moving joint, and allergic reaction. No deaths were associated with STC for joint pain were noted. In 3 of 6 studies comparing stem cell injections to alternative therapies for pain and other outcomes, the review concluded that there is potential but unproven benefit. The comparative effectiveness review concluded that SCT is relatively safe, and there has been no consistent evidence that it causes more complications than standard treatments; however, additional well-designed studies with long-term follow-up are required to compare the efficacy and safety of SCT to other available treatments for spinal disc pain and knee, hip, and shoulder joint pain.

Regenexx® Stem Cell (Regenexx)

Centeno et al. (2018) conducted a RCT to evaluate Regenexx treatment for knee osteoarthritis. Patients with symptomatic knee osteoarthritis were assigned to either an exercise therapy control group (n=22) or a treatment group with image-guided injection of autologous BMC and platelet products (n=26) in this study (n=48). At 3 months, participants were permitted to crossover to the group receiving bone marrow treatment. Measured outcomes included the Knee Society Score, Pain Visual Analogue Scale, Short Form-12 Scales (SF-12), and Lower Extremity Activity Scale. Follow-up for clinical outcomes occurred at 6-weeks, 3, 6, 12 and 24 months. A total of 14 patients were lost to follow-up. All 22 patients in the control group crossed over to BMC treatment after 3 months. Compared to patients who participated in a 3-month home exercise treatment program, those who received a specific protocol of BMC and platelet products had substantial improvements in activity levels, discomfort, range of motion, and stability. Pain decreased in both the exercise therapy and BMC groups, and function improved in the BMC group; nevertheless, these results did not differ substantially between the two groups. Compared to baseline, exercise therapy resulted in significant improvements in range of motion and activity levels at 3 months. There were no reports of major side effects. This RCT is limited by its small sample size and the fact that participants in the exercise group were permitted to switch to the BMC group after three months. To establish safety and efficacy, additional RCTs examining Regenexx techniques, treatments, and products are necessary.

Centeno et al. (2020) published the mid-term results of a RCT comparing the use of BMC and platelet rich plasma versus exercise therapy as treatment for rotator cuff tears (n=25; 14 subjects in the bone marrow group, 11 subjects in the exercise therapy group). The trial is still underway, and the authors highlight that enrollment is ongoing, however, the interim analysis includes the reported results of participants who have reached 12-month follow-up (n=24). The preliminary findings indicate a reduction in the size of most tears following bone marrow treatment, as well as improvements in DASH and NPS scores at 3 and 6 months compared to exercise. However, final outcomes are pending study completion.

Allograft Bone Products Containing Viable Stem Cells

There were no systematic reviews or RCTs that assessed the efficacy of allograft bone products containing viable stem cells for any orthopedic indication. A summary of nonrandomized studies is provided below, organized by product.

National and Specialty Society Guidelines

The **American Association of Orthopedic Surgeons (AAOS)** published evidence-based clinical practice guidelines for the treatment of osteoarthritis of the hip (2017) and knee (2021). Evidence reviews of SCT versus other comparators for these indications did not identify sufficient high-quality evidence to formally address the treatment in their recommendations.

The AAOS published an evidence-based clinical practice guideline on the management of glenohumeral joint

osteoarthritis, which was endorsed by several societies (AAOS, 2020). Injectable biologics, such as stem cells, are not recommended for the treatment of glenohumeral joint osteoarthritis, according to the guideline. The consensus of the panel is that definitive evidence on the efficacy of biologics in glenohumeral osteoarthritis requires improved standardization and high-quality clinical trial evidence.

The strength of evidence was indicated as “No reliable evidence” to determine benefits and harms. Stem cell injection is not mentioned in the guidelines for managing osteoarthritis of the knee (AAOS, 2021) or osteoarthritis of the hip (AAOS, 2017).

The **American College of Rheumatology and Arthritis Foundation (ACRA)** published guidelines on hand, hip, and knee osteoarthritis and strongly advises against stem cell injections in patients with knee and/or hip osteoarthritis, citing "heterogeneity in preparations and lack of standardization of techniques." The guideline made no recommendations for hand because SCT has not been evaluated for this condition (ACRA, 2019).

The **International Society of Stem Cell Research (ISSCR)** published information about stem cell types and uses, stating that there is scant evidence that they are advantageous (ISSCR, 2019). MSC therapy is still in its early stages of development. Various MSCs are thought to have stem cell and immunomodulatory properties that could be used to treat a variety of disorders. The precise nature of these cells, as well as the types of cells they can produce, is unknown. Researchers are in general agreement that not all MSCs are identical, and that their properties vary based on where they originate in the body and how they are isolated and cultivated. Since certain types of stem cells might migrate following transplantation, off-target effects and incorrect integration are possible.

SUPPLEMENTAL INFORMATION

N/A

CODING & BILLING INFORMATION

NOTE: Stem cell therapy applications for orthopedic conditions are not specifically coded. For reporting this procedure, the appropriate CPT code is 20999, or the code for an unlisted procedure of the body part where the procedure is being performed.

CPT Codes

CPT	Description
20939	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (List separately in addition to code for primary procedure)
20999	Unlisted procedure, musculoskeletal system, general
21899	Unlisted procedure, neck or thorax
22899	Unlisted procedure, spine
23929	Unlisted procedure, shoulder
24999	Unlisted procedure, humerus or elbow
25999	Unlisted procedure, forearm or wrist
26989	Unlisted procedure, hands or fingers
27299	Unlisted procedure, pelvis or hip joint
27599	Unlisted procedure, femur or knee
27899	Unlisted procedure, leg or ankle
28899	Unlisted procedure, foot or toes
29999	Unlisted procedure, arthroscopy
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
38241	Bone Marrow or blood-derived peripheral stem cell transplantation; autologous
Not Covered	
0565T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation

0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral
0717T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing and concentration of ADRCs
0718T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral
0737T	Xenograft implantation into the articular surface

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/14/2022 New policy. IRO Peer Review. Oct 28, 2022. Practicing physician Board-certified in Orthopedic Surgery.

REFERENCES

Government Agencies

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   NCD guidelines state coverage for all other indications of stem cell transplantation not otherwise noted as covered or non-covered nationally remain at Medicare Administrative Contractor (MAC) discretion. The orthopedic application of stem-cell therapy is not addressed within the stem cell transplantation NCD.
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Manufacturer/Labeling

1. Regenexx. Available from Regenexx. Accessed October 2022.
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2. Cook J, Young M. Biologic therapies for tendon and muscle injury. Available from UpToDate. Updated August 11, 2022. Accessed October 2022. Registration and login required.

Peer Reviewed Publications

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National and Specialty Organizations

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Ohio Medicaid: All codes that are on the Medicaid Fee schedule will be reviewed for medical necessity and not instantly excluded. This includes 0566T & 0565T for Molina Ohio Medicaid members these are to be reviewed on an individual basis for medical necessity.