# Washington State Health Care Authority

# Health Technology Clinical Committee

 Date:
 June 12, 2020

 Time:
 8:00 a.m. – 12:30 p.m.

 Location:
 Webinar

 Adopted:
 July 10, 2020

# Meeting materials and transcript are available on the HTA website.

# **HTCC Minutes**

<u>Members present:</u> John Bramhall, MD, PhD, Janna Friedly, MD; Chris Hearne, BSN, DNP, MPH; Conor Kleweno, MD; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD MPH; Seth Schwartz, MD, MPH; Mika Sinanan, MD, PhD; Kevin Walsh, MD; Tony Yen, MD

Clinical experts: Paul A. Manner, MD

## **HTCC Formal Action**

- 1. Call to order: Dr. Rege, chair, called the meeting to order; members present constituted a quorum.
- **2. HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines, a high-level overview of the HTA program, how to participate in the HTCC process, and upcoming topics.

### 3. Previous meeting business:

May 15, 2020 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

Action: Ten committee members approved the May 15, 2020 meeting minutes.

# 4. Stem cell therapy for musculoskeletal conditions

**Clinical expert:** The chair introduced Paul A. Manner, MD, Professor, Department of Orthopaedics and Sports Medicine University of Washington School of Medicine.

**Agency utilization and outcomes:** Jason Fodeman, MD, MBA, Associate Medical Director, Department of Labor and Industries, presented the state agency perspective on stem cell therapy for musculoskeletal conditions. Find the full presentation published with the June 12, 2020, meeting materials.

Scheduled and open public comments: Chair called for public comments. Comments provided by:

• Leslie Emerick, Director, Public Policy, WA Acupuncture and Eastern Medicine Association

**Vendor report/HTCC question and answers:** Erika D. Brodt, BS, Aggregate Analytics, Inc., presented the evidence review for stem cell therapy for musculoskeletal conditions. Find the full report published with the <u>June 12, 2020, meeting materials</u>.

### Final

## HTCC coverage vote and formal action:

### **Committee decision**

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on stem cell therapy for musculoskeletal conditions is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of stem cell therapy for musculoskeletal conditions. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover stem cell therapy for musculoskeletal conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Stem cell therapy for musculoskeletal conditions	10	0	0

## Discussion

The committee reviewed and discussed the available studies for use of stem cell therapy for musculoskeletal conditions. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A clinical expert member provided detailed insight and discussion points. All committee members found the evidence sufficient to determine that use of stem cell therapy for musculoskeletal conditions is unproven for efficacy. A majority of committee members found the evidence sufficient to determine the use of stem cell therapy for cost-effectiveness. Based on the evidence presented, all members of the committee found the use of stem cell therapy for musculoskeletal conditions to be either less safe than comparators, or unproven.

# Limitations

N/A

# Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare national or local coverage determination for stem cell therapy for musculoskeletal conditions.

Five evidence based clinical guidelines and consensus statements were identified for this review. The committee discussed guidelines from the following organizations related to the use of stem cells for the treatment of musculoskeletal conditions:

- American Society of Interventional Pain Physicians (ASIP), Responsible, Safe, and Effective Use of Biologics in the Management of Low Back Pain: ASIPP Guidelines, 2019
- International Society for Stem Cell Research (ISSCR), Current State of Cell-based Therapies for Osteoarthritis, 2019

### Final

- Australasian College of Sports Physicians (ACSP), ACSP—Position Statement: The Place of Mesenchymal Stem/Stromal Cell Therapies in Sport and Exercise Medicine, 2016
- International Society for Stem Cell Research (ISSCR), Guidelines for Stem Cell Research and Clinical Translation, 2016
- American Academy of Orthopaedic Surgeons (AAOS), Optimizing Clinical Use of Biologics in Orthopaedic Surgery: Consensus Recommendations From the 2018 AAOS/NIH U-13 Conference, 2018

The committee's coverage determination is consistent with the identified guidelines.

The committee discussion included concerns published by the Food and Drug Administration (FDA), and detailed in the evidence report.

The committee chair directed HTA staff to prepare a findings and decision document on the use of stem cell therapy for musculoskeletal conditions for public comment to be followed by consideration for final approval at the next public meeting.

## 5. Meeting adjourned

### Final

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