Health Technology Clinical Committee
Findings and Decision

Topic: Stem cell therapy for musculoskeletal conditions
Meeting Date: June 12, 2020
Final Adoption: July 10, 2020

Meeting materials and transcript are available on the HTA website.

Number and coverage topic:

20200612A – Stem cell therapy for musculoskeletal conditions

HTCC coverage determination:

Stem cell therapy for musculoskeletal conditions is not a covered benefit.

HTCC reimbursement determination:

Limitations of coverage:

N/A

Non-covered indicators:

N/A

Agency contact information:

<table>
<thead>
<tr>
<th>Agency</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor and Industries</td>
<td>1-800-547-8367</td>
</tr>
<tr>
<td>Public Employees Health Plan</td>
<td>1-800-200-1004</td>
</tr>
<tr>
<td>Washington State Medicaid</td>
<td>1-800-562-3022</td>
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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.

<table>
<thead>
<tr>
<th>Not covered</th>
<th>Covered under certain conditions</th>
<th>Covered unconditionally</th>
</tr>
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<tbody>
<tr>
<td>Stem cell therapy for musculoskeletal conditions</td>
<td>10</td>
<td>0</td>
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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 musculoskeletal conditions is unproven 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
• 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.

Health Technology Clinical Committee Authority:

Washington State’s legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology’s safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.