Policy Name: CLEAR Institute Scoliosis Treatment Protocols
Effective Date: 2/1/2017

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
CLEAR Institute scoliosis treatment protocols are investigative and therefore NOT COVERED, including rehabilitation therapies and/or exercises performed in the clinic or home setting.

The VibeForHealth Scoliosis Traction Chair is investigative and therefore NOT COVERED for all applications, including use in the clinic or home setting.

Description
The CLEAR Institute (St. Cloud, MN) treatment protocol includes a combination of scoliosis-specific physical therapy exercises, chiropractic adjustments, and balance training exercises purported to decrease or eliminate scoliosis curvature and/or deformity. It does not involve standard bracing or corrective surgery. Interventions offered include a combination of the following:

1. Spinal mobility exercises/therapy, including chiropractic adjustments
2. Spinal traction, including cervical traction
3. Vibration therapy
4. Massage therapy
5. Eckard flexion/distraction table therapy
6. Whole body vibration platform therapy
7. Scoliosis Traction Chair (VibeForHealth, St. Cloud MN)

Two treatment plans are available. These are:

1. Standard Care Treatment Plan. Regular visits to the clinic (i.e., approximately three times per week) for four weeks. These are followed by six weeks of twice weekly visits, and then weekly visits for 12 additional weeks.
2. Intensive Care Treatment Plan. This option is provided to individuals who must travel a distance to get to the Institute. Therapy is administered twice daily for a total of one to two weeks.

Both plans have a home rehabilitation protocol that must be performed daily. In certain cases, the Scoliosis Traction Chair is recommended for purchase for home use. Following initial treatment, follow-up assessments are performed and additional therapy may be recommended.
A typical CLEAR treatment session is defined as consisting of three phases:

**Phase 1: Mix.** The body is ‘warmed up’ for treatment, including performing warm-up exercises, massage, and other modalities aimed at relaxing both the spine and surrounding muscles.

**Phase 2: Fix.** Specialized chiropractic manipulations are done using mechanical adjustment instruments aimed at providing adjustments to the spine and other locations (e.g., back, hips)

**Phase 3: Set.** Exercises purported to specialize in influencing posture, balance, and coordination are performed. It is purported that these specialized exercises change how the brain and body work together to achieve and maintain balanced body position.

The program operates under the premise that application of these treatments requires advanced and specialized training, which can be obtained by participation in the CLEAR Certification process. Chiropractor certification is under the auspices of the CLEAR Scoliosis Institute Non-Profit Organization.

CLEAR does not recommend traditional care for treatment of moderate to severe scoliosis, including standard bracing. Prior to an individual beginning CLEAR protocols, the individual or designated representative must sign a waiver stating that they understand this recommendation.

**FDA Approval**

Treatment protocols are not regulated through the FDA approval process.

The FDA has designated certain Class II physical medicine devices exempt from Premarket Notification 510(k) approval, although not exempt from FDA current good manufacturing practice (GMP) regulations. An example of a Class II FDA-exempt device includes electric positioning chairs. The Clear Institute website states that the Scoliosis Traction Chair is “an FDA-registered device, and clinical trials of its effectiveness are ongoing.”

**Prior Authorization**

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT Code**

E1399 – unlisted durable medical equipment

Original Effective Date: 2/1/2017

Re-Review Date(s):