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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
EOS imaging system in children and adolescents with scoliosis

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, “EOS imaging system in children and adolescents with scoliosis” for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Scoliosis

Scoliosis is a deformity of the spine that affects 2 to 4% of adolescents (Reamy & Slakey, 2001; Roach, 1999; Smith, Sciubba, & Samdani, 2008) and can result in cardiopulmonary compromise. It is defined as a lateral curvature of the spine more than 10 degrees with vertebral rotation (Reamy & Slakey, 2001; Roach, 1999; Smith et al., 2008). Males and females are affected equally but evolution of the curve is more frequent in females than males (Miller, 1999). It can be classified as neuromuscular, congenital, or idiopathic which is the most common form of scoliosis (Reamy & Slakey, 2001; Smith, Sciubba, & Samdani, 2008). Idiopathic scoliosis can be categorized as infantile (0 to 3 years), juvenile (4 to 9 years), and adolescent (≥ 10 years); the most common form of idiopathic scoliosis is adolescent idiopathic sclerosis (Reamy & Slakey, 2001; Roach, 1999; Smith et al., 2008).

Scoliosis requires frequent radiographic examination to assess the curve, identify underlying etiology, and help in treatment decision (Yvert et al., 2015). Standard imaging technologies including x-ray film, computed radiography (CR) and digital radiography (DR) have been used for diagnosis and monitoring. Nevertheless, there is growing concern on radiation-based harm on the long-term among children who undergo repeated x-rays (Bone & Hsieh, 2000; Doody et al., 2000). New imaging system, EOS, has been the center of attention with the promise of reducing radiation dose and ensuring higher quality image.

EOS imaging system (From https://www.eos-imaging.com/us/professionals/eos/eos and Wade et al., 2013; McKenna et al., 2012)

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EOS is an X-ray imaging that utilizes slot-scanning technology and is manufactured by EOS imaging (formerly Biospace Med, Paris, France) (Wade et al., 2013). It is a bi-planar technology that is based on two perpendicular fan beams of X-rays and proprietary detectors that travel vertically while scanning the patient. EOS can take posteroanterior (PA) and lateral images concurrently. EOS generates three-dimension images and assessment of individual vertebral rotation can be done. It generates, not only, 2D images similar to conventional imaging techniques, but also produces 3D images that are reconstructed through sterEOS software using the posteroanterior and lateral images, and a 3D statistical spine model. It also permits the rotation of a scoliotic curve with accuracy. EOS system provides low dose stereo-radiographic images. Micro dose option for pediatric follow up exams provides lesser radiation exposure. It is believed that the quality of image is high and therefore improves diagnostics.

EOS is indicated in conditions where frequent x-rays can cause harm due to radiation effect. These diseases include scoliosis (Gummerson & Millner, 2010), the main indication, sagittal deformities (kyphosis), and lower limbs deformities.

EOS is performed while the patient is in an upright, weight-bearing (standing, seated or squatting) position, and can take the entire body or a segment. The physician may choose the adequate position for the exam on the EOS radiolucent chair. The patient stays inside the EOS booth, and then an x-ray of the whole body is taken in less than 20 seconds for an adult and less than 15 seconds for a child. It is believed that EOS eliminates the need for multiple images.

Medical Technology Assessment Committee (MTAC)

Date: 07/09/2018 MTAC REVIEW

EOS imaging system in children and adolescents with scoliosis

Evidence Conclusion:

EOS accuracy

There is a lack of studies comparing the accuracy of EOS to that of standard imaging techniques.

Reproducibility & reliability of EOS 3D spine reconstruction

Rehm et al., 2017

A retrospective study (Rehm et al., 2017) evaluated the interreader reproducibility and reliability of EOS imaging full spine reconstruction in patients with adolescent idiopathic scoliosis (AIS).

Seventy-three consecutive patients (31 men, 42 women) with moderate AIS (mean Cobb angle was 18.2° (range, 9.8°-49.9°)) had their whole spine examined with EOS imaging (AP and lateral). Mean age was 17 years (range 9-58 years). Two readers performed 3D reconstructions of the spine with sterEOS software.

Findings:

Radiation exposure: Mean of total absorbed dose was 593.4 µGy ± 212.3

Mean scan-time: Mean scan-time was 9.5 seconds ±1.7

Reconstruction time: varied significantly between the readers (14.6 min vs 15.2mn P<0.0001)

Inter-reader reproducibility and reliability of every single vertebra rotation from T1-L5: was good to very good for frontal and lateral rotation measurement but limited for axial rotation.

Interclass correlation (ICC) was > 0.80 for all vertebral rotations but for axial rotation it was between 0.51 to 0.88. ICC was ≥0.85 for kyphosis, lordosis, pelvic incidence, sacral slope, pelvic tilt.

Main limitations: Results were limited to patients with moderate scoliosis (mean Cobb angle was 18.2° (range, 9.8°-49.9°)); the study design was retrospective with inherent bias of observational study.

Conclusion: 3D reconstruction of the spine with EOS imaging was reproducible and reliable. Inter-reader reproducibility and reliability of every single vertebra rotation was good but limited for the axial rotation.

Vidal et al., 2013

A reproducibility study (Vidal, Ilharreborde, Azoulay, Sebag, & Mazda, 2013) assessed the reliability of radiographic measurement in adolescent idiopathic scoliosis using EOS system. Seventy-five patients were recruited. Mean age was 12 years, patients had Lenke type 1 or 2 AIS; patients were divided in three groups: AIS group, operated AIS, and control. The authors reported great intra and interobserver reliability in sagittal curvatures, pelvic variables and global sagittal balance. Correlation coefficient was at least 0.85 for each examiner and among the examiners. The main limitation was the lack of comparison with conventional radiographs.

Ilharreborde et al., 2016 (EOS micro dose protocol for the radiological follow-up of adolescent idiopathic scoliosis)

A prospective study evaluated the reliability of EOS x-ray micro dose protocol. The authors included 32 patients who were followed for AIS. All patients underwent EOS x-ray with micro dose protocol and 3D reconstructions were performed. Intrarater and interrater reproducibility were assessed. The authors reported that intraoperator

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repeatability was better than inter-operator reproducibility for all clinical measurements. Interclass correlation (ICC) was >0.91 for all parameters.

Effectiveness – Radiation dose, image quality, patient health outcomes

EOS vs x-ray film or computed radiography

Wade et al., 2013

A systematic review (Wade et al., 2013) assessed the clinical effectiveness of EOS imaging system in children with scoliosis and other orthopedic conditions. A total of three observational studies were included. Inclusion criteria encompassed studies that compared EOS with X-ray film, computed radiography or digital radiography in patients with any orthopedic condition. Studies that reported any outcome were also included. Primary outcome was patient health outcomes; and secondary outcomes were radiation dose and quality of image. The risk of bias of individual studies was overall high.

Study characteristics included: sample size varied from 49 to 140 patients; patients were children and adolescents undergoing follow-up for scoliosis or required spine radiographs for the diagnosis of scoliosis or for follow-up; mean age was 14.7 – 14.8 years (SD 4.8); comparison was done between EOS/earlier version with x-ray film in two studies and with computed radiograph (CR) in one study.

Outcomes:

Patient health outcomes: were not reported

Image quality: comparable or better with EOS; no significance was reported

Radiation dose: was lower with EOS for all comparators (please refer to table below)

Radiation dose results	Mean ESD (mGy); EOS vs film; (Kalifa et al., 1998)	Mean ESD (mGy) second study; EOS vs film	Mean ESD (mGy); EOS vs CR; (Deschenes et al., 2010)
Spine PA	EOS 0.07, film 0.92	EOS 0.23, film 1.2	
Spine lateral	EOS 0.13, film 1.96	EOS 0.37, film 2.3	
Spine AP	EOS 0.08, film 0.93		
Pelvis	EOS 0.06, film 1.13		
Centre of back			EOS 0.18, CR 1.04
Proximal lateral point			EOS 0.27, CR 2.38
Outer side of proximal breast			EOS 0.11, CR 0.83
Proximal anterosuperior iliac spine			EOS 0.16, CR 1.47
Proximal iliac crest			EOS 0.30, CR 2.47
Distal iliac crest			EOS 0.11, CR 0.73
Nape of neck			EOS 0.20, CR 0.59

CR, Computed Radiography; ESD, Entrance Surface Dose;

Conclusion: there was limited data on the clinical effectiveness of EOS. EOS imaging appeared to be comparable or better than x-ray film or computed radiography in children with scoliosis in term of image quality. In addition, radiation dose appeared to be lower for EOS than x-ray or computed radiography. Also, there was no suggestion that the use of EOS enhanced management of scoliosis (from the nature and quality of the image). The long-term benefits from low dose of radiation were also unknown.

Quality assessment: the overall risk of bias was high; due to study design, risk of bias, and precision issues, the quality of evidence from the systematic review was considered low. Eight criteria of AMSTAR were met.

McKenna et al., 2012

This systematic review (McKenna et al., 2012) included the same studies already analyzed in the above systematic review (Wade et al., 2013). Therefore, the conclusion is the same.

Dietrich et al., 2013

A study (Dietrich, Pfirrmann, Schwab, Pankalla, & Buck, 2013) aimed at comparing the radiation dose, workflow, patient comfort of EOS x-ray system and digital radiography. Data of forty-seven consecutive AP and lateral spine radiographs of standard digital radiography were compared to 134 AP and lateral spine radiographs using EOS x-ray system. Outcomes are presented in the following table:

	DR (Digital Radiograph)	EOS x-ray	P-value

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DAP (Dose Area Product)	392.2±231.7 cGy*cm2	158.4±103.8 cGy*cm2	**P<0.001**
Mean examination time	449 ±122 s	248 ±77 s	**P<0.001**
Patients' comfort (noise during examination)	1.4	1.8	**P<0.01**

Table show results for spine radiographs

Limitations: Limitation included: dose area product (DAP) measurement is not the most accurate technique for measuring radiation dose; bias due to baseline confounding, bias in selection of participants into study and measurement bias were not clear; bias due to departures from intended interventions was low; missing data bias and bias in selection of the reported result were low.
Conclusion: Compared to digital radiograph, EOS x-ray system reduces radiation dose and increases noise during examination.
Yvert et al., 2015
A prospective study (see evidence table 1) reported that EOS x-ray may have better or similar image quality than digital radiography with a dynamic flat detector. In addition, no significant difference was reported between the two systems in term of radiation dose.
Hirsch et al., 2016
A prospective study (Hirsch, Ilharreborde, & Mazda, 2016) of 50 patients compared the irradiation dose and reducibility of the cobb angle on bending EOS x-ray and standard x-ray.
Irradiation dose: was five times lower with EOS bending imaging than standard bending x-ray.
Reducibility of Cobb angle: No significant difference was reported.
Patients in this study underwent preoperative assessment for AIS; this included standing AP and lateral EOS x-rays of the spine, standard side-bending x-rays in the supine position, and standing bending x-rays in the EOS booth.
Limitations across studies included study design, sample size, selected outcomes, high risk of bias; literature lacks evidence for clinical outcomes.

Conclusion:

- **Accuracy**
  - There is lack of studies on the test accuracy
- **Reproducibility & reliability of 3D spine reconstruction:**
  - Three observational (one retrospective, two prospective studies) studies were reviewed
  - The studies focused on reliability of spine reconstruction in patients with adolescent idiopathic scoliosis (AIS) using EOS system
  - High inter-reader reproducibility and reliability was reported for all clinical measurements including sagittal curvatures, pelvic variables and global sagittal balance
  - The main limitations resided in the study design and the small sample size
- **Effectiveness – radiation dose, image quality, patient health outcomes**
  - One systematic review and three observational studies were reviewed
  - Radiation dose and image quality were evaluated
  - Comparison was made between EOS x-ray and computed radiography or x-ray film
  - Patients were children and adolescents undergoing follow-up for scoliosis or required spine radiographs for the diagnosis of scoliosis
  - Radiation dose was lower with EOS x-ray than the comparators
  - Image quality was comparable or better with EOS
  - Patient health outcomes: lack of data preclude conclusion on patient health outcomes
  - Data on the association of dose reduction and cancer occurrence were insufficient
  - There was no suggestion that the use of EOS enhances management of scoliosis
- **Evidence**: Overall, evidence is low
- Compared to conventional techniques, EOS system has better or similar image quality and reduces radiation dose. However, the impact of this benefits is not clear.

The use of EOS imaging system in children and adolescents with scoliosis doesn't meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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08/07/2018	08/07/2018 MPC	

MPC Medical Policy Committee

Revision History	Description
08/07/2018	Added MTAC review from 7/9/18 and created document

Codes

No specific codes

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