

screening flexible sigmoidoscopy and screening colonoscopy services, the payment amounts must not exceed the payment rates established for the related diagnostic services.

(5) Section 1833(a)(1) of the Act requires 100 percent payment for preventive services described in section 1861(w)(2) of the Act (excluding electrocardiograms) to which the United States Preventive Services Task Force (USPSTF) has given a grade of A or B for any indication or population. Section 1833(b)(1) of the Act also specifies that the Part B deductible shall not apply with respect to preventive services described in section 1861(w)(2) of the Act (excluding electrocardiograms) to which the USPSTF has given a grade of A or B for any indication or population.

(b) *Scope.* This subpart sets forth—

(1) The scope of ASC services and the criteria for determining the covered surgical procedures for which Medicare provides payment for the associated facility services and covered ancillary services;

(2) The basis of payment for facility services and for covered ancillary services furnished in an ASC in connection with a covered surgical procedure;

(3) The methodologies by which Medicare determines payment amounts for ASC services.

[72 FR 42545, Aug. 2, 2007, as amended at 75 FR 72264, Nov. 24, 2010; 77 FR 68558, Nov. 15, 2012]

#### § 416.161 Applicability of this subpart.

The provisions of this subpart apply to ASC services furnished on or after January 1, 2008.

#### § 416.163 General rules.

(a) Payment is made under this subpart for ASC services specified in §§ 416.164(a) and (b) furnished to Medicare beneficiaries by a participating ASC in connection with covered surgical procedures as determined by the Secretary in accordance with § 416.166.

(b) Payment for physicians' services and payment for anesthesiologists' services are made in accordance with part 414 of this subchapter.

(c) Payment for items and services other than physicians' and anesthesiologists' services, as specified in

§ 416.164(c), is made in accordance with § 410.152 of this subchapter.

#### § 416.164 Scope of ASC services.

(a) *Included facility services.* ASC services for which payment is packaged into the ASC payment for a covered surgical procedure under § 416.166 include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facility where the surgical procedures are performed;

(3) Any laboratory testing performed under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of waiver;

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS), with the exception of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174;

(5) Medical and surgical supplies not on pass-through status under subpart G of part 419 of this subchapter;

(6) Equipment;

(7) Surgical dressings;

(8) Implanted prosthetic devices, including intraocular lenses (IOLs), and related accessories and supplies not on pass-through status under subpart G of part 419 of this subchapter;

(9) Implanted DME and related accessories and supplies not on pass-through status under subpart G of part 419 of this subchapter;

(10) Splints and casts and related devices;

(11) Radiology services for which separate payment is not allowed under the OPPS and other diagnostic tests or interpretive services that are integral to a surgical procedure, except certain diagnostic tests for which separate payment is allowed under the OPPS;

(12) Administrative, recordkeeping and housekeeping items and services;

(13) Materials, including supplies and equipment for the administration and monitoring of anesthesia; and

(14) Supervision of the services of an anesthesiologist by the operating surgeon.

(b) *Covered ancillary services.* Ancillary items and services that are integral to a covered surgical procedure, as

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defined in § 416.166, and for which separate payment is allowed include:

- (1) Brachytherapy sources;
- (2) Certain implantable items that have pass-through status under the OPPS;
- (3) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the acquisition or procurement of corneal tissue for corneal transplant procedures;
- (4) Certain drugs and biologicals for which separate payment is allowed under the OPPS;
- (5) Certain radiology services and certain diagnostic tests for which separate payment is allowed under the OPPS; and
- (6) Non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174.

(c) *Excluded services.* ASC services do not include items and services outside the scope of ASC services for which payment may be made under part 414 of this subchapter in accordance with § 410.152, including, but not limited to—

- (1) Physicians' services (including surgical procedures and all pre-operative and postoperative services that are performed by a physician);
- (2) Anesthetists' services;
- (3) Radiology services (other than those integral to performance of a covered surgical procedure);
- (4) Diagnostic procedures (other than those directly related to performance of a covered surgical procedure);
- (5) Ambulance services;
- (6) Leg, arm, back, and neck braces other than those that serve the function of a cast or splint;
- (7) Artificial limbs;
- (8) Nonimplantable prosthetic devices and DME.

[72 FR 42545, Aug. 2, 2007, as amended at 79 FR 67030, Nov. 10, 2014; 80 FR 70604, Nov. 13, 2015; 83 FR 59178, Nov. 21, 2018; 86 FR 63992, Nov. 16, 2021]

### § 416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* Effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards described in paragraph (b) of this section (whether

commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section.

(b) *General standards.* Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the FEDERAL REGISTER and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

(c) *General exclusions.* Notwithstanding paragraph (b) of this section, covered surgical procedures do not include those surgical procedures that —

- (1) Generally result in extensive blood loss;
- (2) Require major or prolonged invasion of body cavities;
- (3) Directly involve major blood vessels;
- (4) Are generally emergent or life-threatening in nature;
- (5) Commonly require systemic thrombolytic therapy;
- (6) Are designated as requiring inpatient care under § 419.22(n) of this chapter;
- (7) Can only be reported using a CPT unlisted surgical procedure code; or
- (8) Are otherwise excluded under § 411.15 of this chapter.

(d) *Additions to the list of ASC covered surgical procedures.* Surgical procedures are added to the list of ASC covered surgical procedures as follows:

(1) *Pre-proposed rule covered procedures list (CPL) recommendation process.* On or after January 1, 2024, an external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year.

(2) *Inclusion in rulemaking.* If CMS identifies a surgical procedure that meets the requirements at paragraph (a) of this section, including a surgical procedure nominated under paragraph (d)(1) of this section, it will propose to add the surgical procedure to the list of