

## Centers for Medicare & Medicaid Services, HHS

## § 412.87

### PAYMENT ADJUSTMENT FOR CERTAIN CLINICAL TRIAL CASES AND EXPANDED ACCESS USE IMMUNOTHERAPY

#### **§ 412.85 Payment adjustment for certain clinical trial and expanded access use immunotherapy cases.**

(a) *General rule.* For discharges occurring on or after October 1, 2020, the amount of payment for a discharge described in paragraph (b) of this section is adjusted as described in paragraph (c) of this section.

(b) *Discharges subject to payment adjustment.* Payment is adjusted in accordance with paragraph (c) of this section for discharges assigned to MS-DRG 018 involving expanded access use of immunotherapy, or that are part of an applicable clinical trial as determined by CMS based on the reporting of a diagnosis code indicating the encounter is part of a clinical research program on the claim for the discharge.

(c) *Adjustment.* The DRG weighting factor determined under § 412.60(b) is adjusted by a factor that reflects the average cost for cases to be assigned to MS-DRG 018 that involve expanded access use of immunotherapy, or are part of an applicable clinical trial, to the average cost for cases to be assigned to MS-DRG 018 that do not involve expanded access use of immunotherapy and are not part of an applicable clinical trial.

[85 FR 59020, Sept. 18, 2020]

#### **§ 412.83 Payment for extraordinarily high-cost day outliers.**

For discharges occurring before October 1, 1997, if a discharge that qualifies for an additional payment under the provisions of § 412.82 has charges adjusted to costs that exceed the cost outlier threshold criteria for an extraordinarily high-cost case as set forth in § 412.80(a)(1)(ii), the additional payment made for the discharge is the greater of—

(a) The applicable per diem payment computed under § 412.82 (c) or (d); or

(b) The payment that would be made under § 412.84 (i) or (j) if the case had

not met the day outlier criteria threshold set forth in § 412.80(a)(1)(i).

[53 FR 38529, Sept. 30, 1988, as amended at 62 FR 46028, Aug. 29, 1997. Redesignated at 85 FR 59020, Sept. 18, 2020]

#### **412.86 [Reserved]**

### ADDITIONAL SPECIAL PAYMENT FOR CERTAIN NEW TECHNOLOGY

#### **§ 412.87 Additional payment for new medical services and technologies: General provisions.**

(a) *Basis.* Sections 412.87 and 412.88 implement sections 1886(d)(5)(K) and 1886(d)(5)(L) of the Act, which authorize the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the hospital inpatient prospective payment system.

(b) *Eligibility criteria.* For discharges occurring on or after October 1, 2001, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical services and technologies, if the following conditions are met:

(1) A new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

(i) The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

(ii) A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

(A) The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

(B) The new medical service or technology offers the ability to diagnose a

medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.

(C) The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the outcomes described in paragraphs (b)(1)(ii)(C)(I) through (7) of this section.

(1) A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

(2) A decreased rate of at least one subsequent diagnostic or therapeutic intervention.

(3) A decreased number of future hospitalizations or physician visits.

(4) A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time

(5) An improvement in one or more activities of daily living

(6) An improved quality of life

(7) A demonstrated greater medication adherence or compliance.

(D) The totality of the information otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

(iii) Evidence from published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Information source may include the following:

- (A) Clinical trials;
- (B) Peer reviewed journal articles;
- (C) Study results;
- (D) Meta-analyses;
- (E) Consensus statements;

- (F) White papers;
- (G) Patient surveys;
- (H) Case studies;
- (I) Reports;
- (J) Systematic literature reviews;
- (K) Letters from major healthcare associations;

(L) Editorials and letters to the editor; and,

(M) Public comments.

(N) Other appropriate information sources may be considered.

(iv) The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

(v) The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

(2) A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered “new” under the criterion of this section.

(3) The DRG prospective payment rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate, based on application of a threshold amount to estimated charges incurred with respect to such discharges. To determine whether the payment would be adequate, CMS will determine whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75

percent of one standard deviation beyond the geometric mean standardized charge for all cases in the DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant DRGs if the new medical service or technology occurs in many different DRGs). Standardized charges reflect the actual charges of a case adjusted by the prospective payment system payment factors applicable to an individual hospital, such as the wage index, the indirect medical education adjustment factor, and the disproportionate share adjustment factor.

(c) *Eligibility criteria for alternative pathway for certain transformative new devices.* For discharges occurring on or after October 1, 2020, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical devices, if the following conditions are met:

(1) A new medical device is part of the Food and Drug Administration's (FDA) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

(2) A medical device that meets the condition in paragraph (c)(1) of this section will be considered new for not less than 2 years and not more than 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology, the medical technology will no longer be considered "new" under the criterion of this section.

(3) The new medical device meets the conditions described in paragraph (b)(3) of this section.

(d) *Eligibility criteria for alternative pathway for certain antimicrobial products.* (1)(i) A new medical product is designated by FDA as a Qualified Infec-

tious Disease Product and has received marketing authorization for the indication covered by the Qualified Infectious Disease Product designation; or

(ii) For discharges occurring on or after October 1, 2021, a new medical product is approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway.

(2) A medical product that meets the condition in paragraph (d)(1) of this section will be considered new for not less than 2 years and not more than 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology, the medical technology will no longer be considered "new" under the criterion of this section.

(3) The new medical product meets the conditions described in paragraph (b)(3) of this section.

(e) *FDA status requirement.* CMS only considers, for add-on payments for a particular fiscal year, an application for which one of the following conditions are met at the time of new technology add-on payment application submission:

(1) The new medical service or technology is FDA market authorized for the indication that is the subject of the new technology add-on payment application.

(2) The new medical service or technology is the subject of a complete and active FDA marketing authorization request and documentation of FDA acceptance or filing of the request is provided to CMS.

(f) *Announcement of determinations and deadline for consideration of new medical service or technology applications, and conditional approval for certain antimicrobial products.* (1) CMS will consider whether a new medical service or technology meets the eligibility criteria specified in paragraph (b), (c), or

## § 412.88

## 42 CFR Ch. IV (10–1–23 Edition)

(d) of this section and announce the results in the FEDERAL REGISTER as part of its annual updates and changes to the IPPS. CMS will only consider any particular new medical service or technology for add-on payments under paragraph (b), (c), or (d) of this section.

(2) Except as provided for in paragraph (f)(3) of this section, CMS only considers, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA marketing authorization by May 1 prior to the particular fiscal year.

(3) A technology for which an application is submitted under an alternative pathway for certain antimicrobial products under paragraph (d) of this section that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments may be conditionally approved for the new technology add-on payment for that fiscal year, effective for discharges beginning in the first quarter after FDA marketing authorization is granted, provided that FDA marketing authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

[66 FR 46924, Sept. 7, 2001, as amended at 68 FR 45469, Aug. 1, 2003; 69 FR 49243, Aug. 11, 2004; 73 FR 48755, Aug. 19, 2008; 74 FR 43997, Aug. 27, 2009; 82 FR 38511, Aug. 14, 2017; 84 FR 42611, Aug. 16, 2019; 85 FR 59020, Sept. 18, 2020; 88 FR 59331, Aug. 28, 2023]

### § 412.88 Additional payment for new medical service or technology.

(a) For discharges involving new medical services or technologies that meet the criteria specified in § 412.87, Medicare payment will be:

(1) One of the following:

(i) The full DRG payment (including adjustments for indirect medical education and disproportionate share but excluding outlier payments);

(ii) The payment determined under § 412.4(f) for transfer cases;

(iii) The payment determined under § 412.92(d) for sole community hospitals; or

(iv) The payment determined under § 412.108(c) for Medicare-dependent hospitals; plus

(2)(i) *For discharges occurring before October 1, 2019.* If the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(A) 50 percent of the costs of the new medical service or technology; or

(B) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

(ii) *For discharges occurring on or after October 1, 2019.* (A) Except as provided under paragraph (a)(2)(ii)(B) of this section, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(1) 65 percent of the costs of the new medical service or technology; or

(2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

(B) For a medical product designated by FDA as a Qualified Infectious Disease Product or, for discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(1) 75 percent of the costs of the new medical service or technology; or

(2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment.

(b)(1) *For discharges occurring before October 1, 2019.* Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus 50 percent of the estimated costs of the new medical service or technology.

(2) *For discharges occurring on or after October 1, 2019.* Unless a discharge case qualifies for outlier payment under

§ 412.84, Medicare will not pay any additional amount beyond the DRG payment plus—

(i) 65 percent of the estimated costs of the new medical service or technology;

(ii) For a medical product designated by FDA as a Qualified Infectious Disease Product, 75 percent of the estimated costs of the new medical service or technology; or

(iii) For discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, 75 percent of the estimated costs of the new medical service or technology.

[66 FR 46924, Sept. 7, 2001, as amended at 67 FR 50111, Aug. 1, 2002; 69 FR 49244, Aug. 11, 2004; 72 FR 47411, Aug. 22, 2007; 84 FR 42612, Aug. 16, 2019; 85 FR 59021, Sept. 18, 2020]

#### PAYMENT ADJUSTMENT FOR CERTAIN REPLACED DEVICES

#### § 412.89 Payment adjustment for certain replaced devices.

(a) *General rule.* For discharges occurring on or after October 1, 2007, the amount of payment for a discharge described in paragraph (b) of this section is reduced when—

(1) A device is replaced without cost to the hospital;

(2) The provider received full credit for the cost of a device; or

(3) The provider receives a credit equal to 50 percent or more of the cost of the device.

(b) *Discharges subject to payment adjustment.* (1) Payment is reduced in accordance with paragraph (a) of this section only if the implantation of the device determines the DRG assignment.

(2) CMS lists the DRGs that qualify under paragraph (b)(1) of this section in the annual final rule for the hospital inpatient prospective payment system.

(c) *Amount of reduction.* (1) For a device provided to the hospital without cost, the cost of the device is subtracted from the DRG payment.

[72 FR 47411, Aug. 22, 2007]

#### Subpart G—Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Operating Costs

#### § 412.90 General rules.

(a) *Sole community hospitals.* CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, is the sole source of inpatient hospital services reasonably available in a geographic area to Medicare beneficiaries. If a hospital meets the criteria for such an exception under § 412.92(a), its prospective payment rates for inpatient operating costs are determined under § 412.92(d).

(b) *Referral center.* CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital acts as a referral center for patients transferred from other hospitals. Criteria for identifying such referral centers are set forth in § 412.96.

(c) [Reserved]

(d) *Kidney acquisition costs incurred by hospitals with approved kidney transplant programs.* CMS pays for kidney acquisition costs incurred by kidney transplant programs on a reasonable cost basis. The criteria for this special payment provision are set forth in § 412.100.

(e) *Hospitals located in areas that are reclassified from urban to rural.* (1) CMS adjusts the rural Federal payment amounts for inpatient operating costs for hospitals located in geographic areas that are reclassified from urban to rural as defined in subpart D of this part. This adjustment is set forth in § 412.102.

(2) CMS establishes a procedure by which certain individual hospitals located in urban areas may apply for reclassification as rural. The criteria for reclassification are set forth in § 412.103.

(f) *Hospitals that have a high percentage of ESRD beneficiary discharges.* CMS makes an additional payment to a hospital if ten percent or more of its total Medicare discharges in a cost reporting period beginning on or after October 1,