

**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