

HUMAN SERVICES DEPARTMENT[441]**Notice of Intended Action**

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 249A.4, the Department of Human Services proposes to amend Chapter 78, “Amount, Duration and Scope of Medical and Remedial Services,” Iowa Administrative Code.

The proposed amendment of paragraph 78.1(20)“a” adds diagnoses/conditions that will be covered for allogeneic and autologous bone marrow transplants, now generally known as “stem cell” transplants. Changes are also being made to the subparagraph pertaining to heart transplants to make, with preprocedure review, artificial hearts and ventricular assist devices (VADs) covered as temporary life-support systems until a human heart becomes available for transplant and to add introductory language that describes the general types of medical circumstances for which heart transplants are allowed, consistent with existing language for other types of transplants addressed in the rules. Lastly, a technical correction is being made to change an existing reference to “Iowa Foundation for Medical Care” to the “Iowa Medicaid enterprise medical services prior authorization unit.”

The Department is updating current tissue and organ transplant rules to reflect current standards of care. These changes are also being made to reduce the number of requests for exceptions to policy the Department receives, which are routinely approved, for these transplants.

Any interested person may make written comments on the proposed amendment on or before December 3, 2013. Comments should be directed to Harry Rossander, Bureau of Policy Coordination, Department of Human Services, Hoover State Office Building, 1305 East Walnut Street, Des Moines, Iowa 50319-0114. Comments may be sent by fax to (515)281-4980 or by e-mail to policyanalysis@dhs.state.ia.us.

This amendment does not provide for waiver in specified situations because the amendment confers a benefit on the affected providers and Medicaid members by allowing coverage for additional diagnoses/conditions for stem cell transplants. Similarly, the amendment confers a benefit on providers and members relative to coverage of artificial hearts and VADs under regular policy as temporary life-support systems, with preprocedure review. Finally, this amendment does not provide for waiver in specified situations because such waiver may be requested under the Department’s general rule on exceptions at rule 441—1.8(17A,217).

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code section 249A.4.

The following amendment is proposed.

Amend paragraph **78.1(20)“a”** as follows:

a. Payment will be made only for the following organ and tissue transplant services:

- (1) No change.
- (2) Allogeneic bone marrow stem cell transplants for the treatment of aplastic anemia, severe combined immunodeficiency disease (SCID), Wiskott-Aldrich syndrome, follicular lymphoma, Fanconi anemia, paroxysmal nocturnal hemoglobinuria, pure red cell aplasia, amegakaryocytosis/congenital thrombocytopenia, beta thalassemia major, sickle cell disease, Hurler’s syndrome (mucopolysaccharidosis type 1 [MPS-1]), adrenoleukodystrophy, metachromatic leukodystrophy, refractory anemia, agnogenic myeloid metaplasia (myelofibrosis), familial erythrophagocytic lymphohistiocytosis and other histiocytic disorders, acute myelofibrosis, Diamond-Blackfan anemia, epidermolysis bullosa, or the following types of leukemia: acute myelocytic

~~leukemia in relapse or remission, chronic myelogenous leukemia, juvenile myelomonocytic leukemia, chronic myelomonocytic leukemia, acute myelogenous leukemia, and acute lymphocytic lymphocytic leukemia in remission.~~

(3) ~~Autologous bone marrow stem cell transplants for treatment of the following conditions: acute leukemia in remission with a high probability of relapse when there is no matched donor; chronic lymphocytic leukemia; plasma cell leukemia; resistant non-Hodgkin's lymphomas; Hodgkin's lymphoma; relapsed Hodgkin's lymphoma; lymphomas presenting poor prognostic features; follicular lymphoma; recurrent or refractory neuroblastoma; medulloblastoma; or advanced Hodgkin's disease when conventional therapy has failed and there is no matched donor; primitive neuroendocrine tumor (PNET); atypical/rhabdoid tumor (ATRT); Wilm's tumor; Ewing's sarcoma; metastatic germ cell tumor; or multiple myeloma.~~

(4) No change.

(5) ~~Heart transplants for persons with inoperable congenital heart defects, heart failure, or related conditions. Artificial hearts and ventricular assist devices, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplants, are not covered. Artificial hearts and ventricular assist devices as a permanent replacement for a human heart are not covered.~~ Heart-lung transplants are covered where bilateral or unilateral lung transplantation with repair of a congenital cardiac defect is contraindicated.

~~Heart transplants, and heart-lung transplants, artificial hearts, and ventricular assist devices described above require preprocedure review by the Iowa Foundation for Medical Care Medicaid enterprise medical services prior authorization unit. (Cross-reference 78.1(19) and 78.28(1)“f.”)~~ Covered heart transplants are payable only when performed in a facility that meets the requirements of 78.3(10).

(6) and (7) No change.