

Rare Diseases

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Authority: [32 CFR 199.2\(b\)](#) and [32 CFR 199.4\(g\)\(15\)](#)

1.0 DESCRIPTION

TRICARE defines a rare disease as any disease or condition that affects less than 200,000 persons in the United States.

2.0 POLICY

2.1 Coverage for treatment of rare diseases may be considered on a case-by-case basis. Case-by-case review is not required for drugs, devices, medical treatments, and procedures that have already been established as safe and effective for treatment of rare diseases.

2.1.1 In reviewing the case, any or all of the following sources may be used to determine if the proposed benefit is considered safe and effective.

2.1.2 Trials published in refereed medical literature.

2.1.3 Formal technology assessments.

2.1.4 National medical policy organization positions.

2.1.5 National professional associations.

2.1.6 National expert opinion organizations.

2.2 If case review indicates that the proposed benefit for a rare disease is safe and effective for that disease, benefits may be allowed. If benefits are denied, an appropriate appealing party may request an appeal.

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