Medicare Program

List of Orphan Drugs with Increased Applicable Percentage for Calendar Quarters in 2023

The increased applicable percentage for orphan drugs, set at 26 percent for those furnished to fewer than 100 unique beneficiaries per calendar year, was finalized in the CY 2024 rulemaking and codified at §414.940(d)(5). To qualify, a drug must have an orphan drug designation under section 526 of the Federal Food, Drug, and Cosmetic Act and must also be approved by the FDA exclusively for indications within the designated rare disease or condition. The following are a list of drugs that meet these requirements for calendar quarters in 2023.

HCPCS	Healthcare Common Procedure Coding System (HCPCS) Descriptor (new HCPCS code(s) in BOLD)
J0208	Injection, Sodium Thiosulfate, 100 Mg
J0223	Injection, Givosiran, 0.5 Mg
J0224	Injection, Lumasiran, 0.5 Mg
J0584	Injection, Burosumab-Twza 1 Mg
J0596	Injection, C1 Esterase Inhibitor (Recombinant), Ruconest, 10 Units
J0597	Injection, C-1 Esterase Inhibitor (Human), Berinert, 10 Units
J0840	Injection, Crotalidae Polyvalent Immune Fab (Ovine), Up To 1 Gram
J1305	Injection, Evinacumab-Dgnb, 5mg
J1640	Injection, Hemin, 1 Mg
J1743	Injection, Idursulfase, 1 Mg
J1746	Injection, Ibalizumab-Uiyk, 10 Mg
J1931	Injection, Laronidase, 0.1 Mg
J2787	Riboflavin 5'-Phosphate, Ophthalmic Solution, Up To 3 Ml
J2860	Injection, Siltuximab, 10 Mg
J7170	Injection, Emicizumab-Kxwh, 0.5 Mg
J7202	Injection, Factor Ix, Albumin Fusion Protein, (Recombinant), Idelvion, 1 I.U.
J9032	Injection, Belinostat, 10 Mg
J9057	Injection, Copanlisib, 1 Mg
J9153	Injection, Liposomal, 1 Mg Daunorubicin And 2.27 Mg Cytarabine
J9203	Injection, Gemtuzumab Ozogamicin, 0.1 Mg
J9262	Injection, Omacetaxine Mepesuccinate, 0.01 Mg
J9268	Injection, Pentostatin, 10 Mg
J9269	Injection, Tagraxofusp-Erzs, 10 Micrograms
J9295	Injection, Necitumumab, 1 Mg
J9313	Injection, Moxetumomab Pasudotox-Tdfk, 0.01 Mg
J9331	Injection, Sirolimus Protein-Bound Particles, 1 Mg