

Hyqvia[®] (immune globulin infusion 10% [human] with recombinant human hyaluronidase) – Expanded Indication

- On April 11, 2023, <u>Takeda announced</u> the FDA approval of <u>Hyqvia (immune globulin infusion 10% [human] with recombinant human hyaluronidase</u>), for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
 - Previously, Hyqvia was only approved for this indication in adults.
 - The safety and efficacy of chronic use of Recombinant Human Hyaluronidase in Hyqvia have not been established in conditions other than PI.
- The approval of Hyqvia's expanded indication was based on an open-label, non-controlled study in 44 PI patients between the age of 2 to 16. The primary endpoint was the rate of acute serious bacterial infections (aSBI), per subject per year.
 - During the 12-month trial period, the mean aSBI rate per year was 0.04 (with an upper 1sided 99% confidence interval of 0.21, p < 0.001), which met the predefined success rate of less than one aSBI per subject per year.
 - The mean rate of all infections per subject-year was 3.20, with an upper limit of the 95% CI of 4.05.
- Hyqvia carries a boxed warning for thrombosis.
- Hyqvia is administered subcutaneously via an infusion pump, with weight-based dosing. For complete dosing and administration recommendations, refer to the Hyqvia drug label.



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