

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: chorionic gonadotropin for injection (Pregnyl® – Organon; Novarel® - Ferring, generics) Dispensing Limit

DATE REVIEWED: 08/19/2019

DESCRIPTION

Chorionic gonadotropin (Pregnyl, Novarel, generic) 10,000 units

Maximum quantity per RX = 3 vials

This product is available in a vial containing 10,000 USP units of chorionic gonadotropin. For two of the three FDA approved indications, prepubertal cryptorchidism not due to anatomical obstruction and selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency) in males, there are several advocated dosage regimens. Most advocated dosing regimens for these two indications require between 6,000 to 48,000 USP units per month of therapy. In the third FDA approved indication, induction of ovulation and pregnancy, the manufacturer recommended dose is 5,000 to 10,000 USP units one day following the last dose of menotropins per month. Hence, 3 vials (30,000 USP units) would supply enough drug for one month of therapy for most advocated regimens for prepubertal cryptorchidism and hypogonadotropic hypogonadism in males and it would also be adequate for the induction of ovulation.

CRITERIA

All approvals are provided for 12 months in duration unless otherwise noted below.

Indication:

1. Induction of ovulation and pregnancy: Express Scripts recommends not to override this quantity limit.
2. Prepubertal cryptorchidism not due to anatomical obstruction: Approve the quantity requested, not to exceed a total of 4 vials per dispensing.
3. Hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency): Approve the quantity requested, not to exceed a total of 6 vials per dispensing.

Chorionic gonadotropin (Novarel) 5,000 units

Maximum quantity per RX = 6 vials

This product is available in a vial containing 5,000 USP units of chorionic gonadotropin. For two of the three FDA approved indications, prepubertal cryptorchidism not due to anatomical obstruction and selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency) in males, there are several advocated dosage regimens. Most advocated dosing regimens for these two indications require between 6,000 to 48,000 USP units per month of therapy. In the third FDA approved indication, induction of ovulation and pregnancy, the manufacturer recommended dose is 5,000 to 10,000 USP units one day following the last dose of menotropins per month. Hence, 6 vials (30,000 USP units) would supply enough drug for one month of therapy for most advocated regimens for prepubertal cryptorchidism and hypogonadotropic hypogonadism in males and it would also be adequate for the induction of ovulation.

CRITERIA

All approvals are provided for 12 months in duration unless otherwise noted below.

Indication:

1. Induction of ovulation and pregnancy: Express Scripts recommends not to override this quantity limit.
2. Prepubertal cryptorchidism not due to anatomical obstruction: Approve the quantity requested, not to exceed a total of 8 vials per dispensing.
3. Hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency): Approve the quantity requested, not to exceed a total of 12 vials per dispensing.

REFERENCES

1. Novarel[®] injection [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; May 2018.
2. Pregnyl[®] injection [prescribing information]. Roseland, NJ: Organon USA Inc.; January 2015.
3. Chorionic gonadotropin for injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; February 2016.