PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**GONADOTROPIN**
BRAND NAME **(generic)**	**PREGNYL** **(chorionic gonadotropin- hCG)** **NOVAREL** **(chorionic gonadotropin- hCG)** **chorionic gonadotropin- hCG**
Status: CVS Caremark Criteria	***Med D***
Type: Initial Prior Authorization	***Ref # 545-A***

FDA-APPROVED INDICATIONS

1. Prepubertal cryptorchidism not due to anatomical obstruction. In general, HCG is thought to induce testicular descent in situations when descent would have occurred at puberty. HCG thus may help predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following HCG administration is permanent, in most cases, the response is temporary. Therapy is usually instituted between the ages four and nine.
2. Selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males.
3. Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins.

Hcg has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or ‘‘normal’’ distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets.

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of hypogonadotropic hypogonadism? [If yes, then skip to question 3.]	Yes	No
2	Does the patient have a diagnosis of prepubertal cryptorchidism? [If no, then no further questions.]	Yes	No
3	Is the requested drug being prescribed for induction of ovulation?	Yes	No

Guidelines for Approval			
Duration of Approval 12 Months			
Set 1: Hypogonadotropic hypogonadism		**Set 2: Prepubertal cryptorchidism**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	3	2	1
			3

Mapping Instructions		
	Yes	**No**
1.	Go to 3	Go to 2
2.	Go to 3	Deny
3.	Deny	Approve, 12 months

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Pregnyl [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; January 2015.
2. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; May 2018.
3. Chorionic Gonadotropin for Injection [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; February 2016.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (GY) 08/2010
Revised:	MG 07/2003, 02/2005; CT 03/2006, MG 03/2007, 04/2008; MR 04/2009; GY 03/2010, GY 08/2010, TG 05/2011, 09/2011 (CMS); AC 09/2012 (CMS); WH 09/2013; KF 09/2014 (CMS), TS 12/2014, TS 08/2015 (CMS); JP 12/2015, 06/2016 (CMS), IP 11/2016, 07/2017 (CMS), NU 03/2018, BI 06/2018 (CMS), JL 10/2018, 06/2019 (CMS); SP 10/2019, 05/2020 (CMS), BMW 05/2021 (v2 annual, no clinical changes), KC 02/2022 (annual, no changes), BMW 05/2022 (annual), KG 02/2023 (annual, no changes)
Reviewed:	CRC: 12/2001, 07/2003; CDPR: 02/2005, 03/2006 CDPR; WLF 04/2008, 06/2009, 04/2010; KP 09/2010, 06/2011, 06/2012; LMS 06/2013, 12/2013, SES 12/2014; MC 12/2015; ME 12/2016, JG 03/2018, DNC 11/2018, DNC 10/2019, DNC 05/2021, DC 02/2022, SNG 05/2021, AN 02/2023
External Review:	12/2001, 08/2005, 07/2008, 9/2009, 09/2010, 09/2011, 10/2012, 07/2013, 02/2014, 01/2015, 01/2016, 01/2017, 03/2018, 12/2018, 12/2019, 07/2021, 07/2022, 04/2023