CareFirst Family of health care plans

CVS caremark™

PRIOR AUTHORIZATION CRITERIA

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

FDA-APPROVED INDICATIONS[1,2]

Prepubertal cryptorchidism

Prepubertal cryptorchidism not due to anatomic obstruction. In general, human chorionic gonadotropin (hCG) is thought to induce testicular descent in situations when descent would have occurred at puberty. Human chorionic gonadotropin thus may help to 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 of 4 and 9.

Hypogonadotropic hypogonadism

Selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males.

Human chorionic gonadotropin has not been demonstrated to be effective adjunctive therapy in the treatment of obesity.[1,2] 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, skip to question 3.]	Yes	No
2	Does the patient have a diagnosis of prepubertal cryptorchidism? [If no, no further question.]	Yes	No
3	Is the patient male?	Yes	No

Guidelines for Approval	
Duration of Approval	**12 Months**
Set 1	**Set 2**

Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	2	1
3		3	

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

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.; January 2015.

DOCUMENT HISTORY

Written: Specialty Clinical Development (JG) 12/2001

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)

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

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