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MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** guanfacine ER (INTUNIV®)
PAGE: 1 of 3	**REFERENCE NUMBER:** NH.PMN.37
EFFECTIVE DATE: 04/10	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 05/14, 08/16
PRODUCT TYPE: Medicaid	**REVISED:** 05/11, 05/12, 05/13, 07/17

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

Description: INTUNIV® is an oral, centrally-acting, alpha-2 adrenergic receptor agonist and is used in the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy or as an adjunctive to stimulant medication

Brand: guanfacine ER (INTUNIV®): 1mg, 2mg, 3mg, 4mg tablets

FDA Labeled Indications: Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ≥ 6 years of age and ≤ 17 years of age.

Criteria for Approval:

A. Diagnosed by a pediatrician, family physician, or mental health care provider with experience in the treatment of ADHD **AND;**
B. Patient is ≥ 6 years **AND;**
C. Must have documented failure of Preferred Drug List (PDL) ADHD stimulants at maximum tolerated doses, one medication **EACH** from the amphetamine class (Adderall XR, Dexedrine SR) **AND** the methylphenidate class (Concerta, Metadate CD), **OR** have contraindications that preclude the

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use of stimulants **AND;**

D. Must have documented failure after trial of guanfacine regular release with twice daily – three times daily dosing unless clinically significant adverse effects are experienced.
E. Use of clonidine and guanfacine concurrently will not be approved as it is considered duplicate therapy.

Approval: Initial Approval: 6 months for once daily dosing.
Continued Approval: 12 months for once daily dosing. If documentation shows improvement of ADHD treatment measures as evidenced by psychological, educational and social indicators, adherence to therapy and progress notes reflecting no adverse events.

Special Instructions

- Pregnancy category B.
- See prescribing information for dosing, precautions, and warnings.
- Use INTUNIV® with caution in patients at risk for hypotension, bradycardia, heart block, or syncope (e.g., those taking antihypertensives).
- DO NOT substitute Intuniv for immediate-release guanfacine on a milligram-per-milligram basis because of differing pharmacokinetic profiles. See package insert for recommended transition schedule.
- Dosage adjustment needed with concomitant use of strong CYP3A4 inhibitors or inducers. See package insert for specifics and dosage adjustments.
- If discontinuing, taper the dose in decrements of no more than 1 mg every 3 to 7 days.
- The safety and efficacy of INTUNIV® in the adult population (≥ 18 years of age) has not been established.

References:

1. INTUNIV® monograph, Clinical Pharmacology, accessed April 2014, www.clinicalpharmacology.com .
2. INTUNIV® prescribing information, accessed April, 2014 at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022037s009lbl.pdf

3. Scahill L, et. al. A placebo-controlled study of guanfacine in the treatment of children with tic disorders and attention deficit hyperactivity disorder. Am J Psychiatry. 2001 Jul; 158(7):106774.
4. Pliszka S; AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2007 Jul; 46(7):894-921.

Revision Log	
Revision	**Date**
Removed mono-therapy required trial. Once daily dosing specified in the "Approval" section.	05/11
References updated to reflect current literature search.	05/11
Added language "at maximized tolerated doses" to stimulant trial.	05/12
References updated to reflect current literature search.	05/12
References updated to reflect current literature search.	05/13
Added warning regarding need for dosage adjustment with CYP3A4 inhibitors and inducers	05/13
Added warnings regarding substitution of immediate-release guanfacine for long-acting guanfacine without dosage adjustment.	05/13
Updated references.	05/14
Removed specific lengths of drug trial required under Criteria for Approval for items C and D: "for a MINIMUM of two weeks" and "a MINIMUM 4 week"	08/15
Annual review. No changes	08/16
Initial: Removed less than 17 years of age criteria; updated requirement related to immediate-release guanfacine trial to include "unless clinically significant adverse effects are experienced".	07/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file