



# Independence Blue Cross

**Policy Title** Guanfacine Extended Release (Intuniv™)

**Policy Number** FS.CLIN.93

**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification and age, gender or quantity restrictions. Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

<b>Policy</b>	<p><b>Guanfacine Extended Release (Intuniv™)</b> is indicated for the treatment of attention deficit hyperactivity disorder (ADHD).</p> <p>The use of Guanfacine Extended Release (Intuniv™) requires prior authorization (i.e. clinical pharmacy and/or medical director review).</p>
<b>Policy description</b>	<p><b>Guanfacine Extended Release (Intuniv™)</b> is a selective alpha 2A adrenergic receptor agonist. Guanfacine Extended Release (Intuniv™) is not a central nervous system stimulant and the mechanism of action in ADHD is not known.</p>
<b>Policy guideline inclusion</b>	<p><b>Guanfacine extended release (Intuniv)</b> is approved when there is documentation of a diagnosis of ADHD and one of the following inclusion criteria is met:</p> <ul style="list-style-type: none"> <li>• Documentation of a trial and failure or contraindication/intolerance/allergy to any two of the following medications:             <ul style="list-style-type: none"> <li>○ A methylphenidate containing product</li> <li>○ A mixed amphetamine salts containing product (eg, amphetamine-dextroamphetamine [Adderall or Adderall XR])</li> <li>○ Atomoxetine hydrochloride (Strattera®)</li> <li>○ A dextroamphetamine containing product</li> <li>○ Methamphetamine hydrochloride (Desoxyn®)</li> <li>○ A dexmethylphenidate containing product</li> </ul> </li> <li>• Documentation of a history of or a potential for drug abuse among the individual or a member of the individual's household</li> </ul>
<b>Policy guideline exclusion</b>	<p><b>Guanfacine extended release (Intuniv)</b> is denied when both of the following exclusion criteria are present:</p> <ul style="list-style-type: none"> <li>• No documentation of a diagnosis of ADHD and no documentation of a</li> </ul>

	<p>trial and failure or contraindication/intolerance/allergy to any two of the following medications:</p> <ul style="list-style-type: none"> <li>○ A methylphenidate containing product</li> <li>○ A mixed amphetamine salts containing product (eg, amphetamine-dextroamphetamine [Adderall or Adderall XR])</li> <li>○ Atomoxetine hydrochloride (Strattera®)</li> <li>○ A dextroamphetamine containing product</li> <li>○ Methamphetamine hydrochloride (Desoxyn®)</li> <li>○ A dexmethylphenidate containing product</li> </ul> <ul style="list-style-type: none"> <li>• No documentation of a diagnosis of ADHD and no documentation of a history of or a potential for drug abuse among the individual or a member of the individual's household</li> </ul>				
<b>Policy List of Applicable Drugs</b>	<table border="1"> <thead> <tr> <th>Brand name</th> <th>Generic name</th> </tr> </thead> <tbody> <tr> <td>Intuniv</td> <td>Guanfacine extended release</td> </tr> </tbody> </table>	Brand name	Generic name	Intuniv	Guanfacine extended release
Brand name	Generic name				
Intuniv	Guanfacine extended release				
<b>Dosing and administration</b>	Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.				
<b>Policy references</b>	<p>American Academy of Family Physicians guidelines on the treatment of children with ADHD. Available at <a href="http://www.aafp.org">www.aafp.org</a>. accessed May 16,2011.</p> <p>American Academy of Pediatrics Clinical practice guideline: treatment of the school aged child with attention deficit/hyperactivity disorder. Pediatrics. 108;4. 2001; 1033-1044.</p> <p>Biederman J, Melmed R, Patel A. et al. A randomized, double blind placebo controlled study of guanfacine extended release in children and adolescents with ADHD. Pediatrics 121; 2008: e73-e84.</p> <p>Facts and Comparisons website [Intuniv]. Available at <a href="http://www.factsandcomparisons.com">www.factsandcomparisons.com</a>. Accessed May 16,2011.</p> <p>Intuniv [package insert]. Wayne PA. Shire Pharmaceuticals. 2009.</p> <p>Sallee F, Lyne A, Wigal T. et al. Long term safety and efficacy of guanfacine extended release in children and adolescents with ADHD. Journal of child and adolescent psychopharmacology. 19. 2009; 215-226.</p>				
<b>Policy link to related policies</b>					
<b>Version effective date</b>	06/09/2011				

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