

DCF PMAC: Medications Considered for Addition to the Approved Drug List
Updated June 2016

Drug Considered (Generic)	Date of Review	Approved	Rationale (additional details available upon request)
Aripiprazole long acting inj	4/4/2014, 06/03/2016	Y	Restricted to adolescents.
Aripiprazole ER IM	3/4/2016, 06/03/2016	Y	Restricted to adolescents.
Asenapine	3/5/2010, 5/6/2011, 4/10/2015	Y	Restricted to children/adolescents 10-17 years of age.
Atenolol	9/4/2009	N	Removed due to lack of safety data and experience with use in children and adolescents.
Brexipiprazole	3/4/2016	N	Lack of safety and efficacy data in children and adolescents.
Cariprazine	3/4/2016	N	Lack of safety and efficacy data in children and adolescents.
Duloxetine	6/5/2015	Y	Approved as per FDA approval restricted to: GAD, Ages 7-17
Felbamate	10/8/2004	N	No indication for use as a psychotropic medication in children.
Fluphenazine decanoate	4/4/2014	Y	Only for children >=13yrs old.
Gabapentin	5/23/2014	N	Lack of safety and efficacy data in children and adolescents.
Guanfacine XR	2/5/2010	Y	Safety and efficacy data now available. Reviewed and approved.
Haloperidol decanoate	4/4/2014	Y	Only for children >=13yrs old.
Herbals/Nutritional Suppl	4/1/2005	N	Not under perview of PMAC as they are not FDA regulated medications/possible inconsistency in formulations of the same product.
lloperidone	3/5/2010, 4/10/2015	N	Lack of safety-efficacy data in children and or adolescents. Need for careful titration is a concern. QTC interval and orthostasis are a concern.
Lamotrigine XR	8/6/2010	Y	But with a warning for use in children <13yrs old dure to lack of evidence for safety and efficacy in this age group.
Lurasidone	5/6/2011, 10/5/2012, 4/10/2015, 4/1/2016	N	Studies published to date do not indicate efficacy in treatment of children or adolescents.
Melatonin	1/6/06, 5/5/06, 1/6/08	N	Not under perview of PMAC: not an FDA regulated medication/possible inconsistency in formulations of the same product.
Methylphenidate ER liquid	4/5/2013	Y	Similar to other methylphenidate products already approved.
Metoprolol	9/4/2009	N	Removed due to lack of safety data and experience with use in children and adolescents.
Molindone	12/4/2009	Y	Associated with weight loss vs. gain. To remain on the approved drug list.
Molindone	11/5/2010	N	No longer available on the market.
Nadolol	1/7/2011	N	Removed due to lack indication for use in children and adolescents.
Nefazodone	8/5/2004, 06/05/2015, 06/03/2016	N	ADR profile: Liver toxicity.
Olanzapine long acting inj	4/4/2014, 06/03/2016	N	Lack of safety and efficacy data in children and adolescents.
Olanzapine	2/5/2010	Y	On approved list but restricted to DCF MD review. Based on FDA required change in prescribing information relating to weight gain.
Oxcarbazepine	12/1/2006, 5/1/2009, 5/7/2010, 12/6/2013, 5/1/2015	N	Lack of safety-efficacy data in children. No new data available since last review.
Paliperidone	9/4/2009 & 5/6/2011	Y	Lack of safety-efficacy data in children. Now has FDA approval for use in children.
Paliperidone long acting inj	4/4/2014, 06/03/2016	Y	Restricted to adolescents.
Paroxetine	3/5/2004, 06/05/2015, 06/03/2016	N	Higher risk of suicide per FDA advisory. Reports of liver failure. Study show to be ineffective and unsafe.
Pemoline	8/5/2004	N	Withdrawn from market
Pimozide	9/5/2008	N	ADR profile: EKG changes - QT prolongation.
Prazosin	6/5/2009 & 2/1/13	Y	Approved with age based max dosing
Risperidone long acting inj	4/4/2014	Y	Only for children >=13yrs old.
Ramelteon	9/4/2009	N	Lack of safety-efficacy data in children. Data may be available Feb 2010.
Thioridazine	8/5/2004	N	ADR profile: EKG changes - QT prolongation.
Tiagabine	10/8/2004, 5/1/2015	N	Lack of data re safety and efficacy in children for psychiatric indications.
Topiramate	12/1/2006, 5/1/2015	N	Lack of data re efficacy in children for psychiatric indications.
Trazodone XR	8/6/2010, 06/03/2016	N	No advantage over trazodone IR when used for insomnmnia.
Venlafaxine	3/5/2004 & 5/6/2011	Y	Higher risk of suicide per FDA advisory. New Study shows acceptable safety and efficacy.
Verapamil	1/7/2011	N	Removed due to lack indication for use in children and adolescents.
Vilazodone	10/5/2012, 06/03/2016	N	No posted results from prevous study. Recruitment underway for 3 new studies.
Zaleplon	5/1/2015	N	Removed due to lack of data regarding use in children/adolescents.
Zolpidem	5/1/2015	N	Removed: study of 201 children showed no efficacy and significant adverse drug reactions.