

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

Drug Considered (Brand)	Drug Considered (Generic)	Date of Review	Approved	Rationale (additional details available upon request)
Cylert	Pemoline	08/05/2004	N	Withdrawn from market
Cymbalta	Duloxetine	2/4/05 & 5/5/06	N	Lack of data re safety and efficacy in children for psychiatric indications.
Cymbalta	Duloxetine	05/07/2010	N	Only 1 Lilly sponsored study completed. Additional studies in pipeline. Deny approval until efficacy data is available.
Effexor	Venlafaxine	03/05/2004	N	Higher risk of suicide per FDA advisory.
Fanapt	Iloperidone	03/05/2010	N	Lack of safety-efficacy data in children. Clinical trials not impressive. Need for careful titration is a concern. QTC interval is a concern.
Felbatol	Felbamate	10/08/2004	N	No indication for use as a psychotropic medication in children.
Gabitril	Tiagabine	10/08/2004	N	Lack of data re safety and efficacy in children for psychiatric indications.
Herbals/Nutritional Suppl	Herbals/Nutritional Suppl	04/01/2005	N	Not under perview of PMAC as they are not FDA regulated medications/possible inconsistency in formulations of the same product.
Intuniv	Guanfacine XR	10/09/2009	N	Pending further data once drug is actually available.
Intuniv	Guanfacine XR	02/05/2010	Y	Safety and efficacy data now available. Reviewed and approved.
Invega	Paliperidone	09/04/2009	N	Lack of safety-efficacy data in children.
Melatonin	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.
Mellaril	Thioridazine	08/05/2004	N	ADR profile: EKG changes - QT prolongation.
Lopressor	Metoprolol	09/04/2009	N	Removed due to lack of safety data and experience with use in children and adolescents.
Minipres	Prazosin	06/05/2009	N	Restricted with caution. Dosing and efficacy data in children not available.
Moban	Molindone	12/04/2009	Y	Associated with weight loss vs. gain. To remain on the approved drug list.
Orap	Pimozide	09/05/2008	N	ADR profile: EKG changes - QT prolongation.
Paxil	Paroxetine	03/05/2004	N	Higher risk of suicide per FDA advisory.
Rozerem	Ramelteon	09/04/2009	N	Lack of safety-efficacy data in children. Data may be available Feb 2010.
Saphras	Asenapine	03/05/2010	N	No safety-efficacy data for children available. Clinical trials not impressive. Concern over SL-buccal dosage form.
Serzone	Nefazodone	08/05/2004	N	ADR profile: Liver toxicity.
Tenormin	Atenolol	09/04/2009	N	Removed due to lack of safety data and experience with use in children and adolescents.
Topamax	Topiramate	12/01/2006	N	Lack of data re efficacy in children for psychiatric indications.
Trileptal	Oxcarbazepine	12/01/2006	N	Lack of data re efficacy in children for psychiatric indications.
Trileptal	Oxcarbazepine	5/1/2009, 5/7/2010	N	Lack of safety-efficacy data in children. No new data available since last review.
Zyprexa	Olanzapine	02/05/2010	Y	On approved list but restricted to DCF MD review. Based on FDA required change in prescribing information relating to weight gain.
Drug Considered (Generic)	Drug Considered (Brand)	Date of Review	Approved	Rationale (additional details available upon request)
Asenapine	Saphras	03/05/2010	N	No safety-efficacy data for children available. Clinical trials not impressive. Concern over SL-buccal dosage form.
Atenolol	Tenormin	09/04/2009	N	Removed due to lack of safety data and experience with use in children and adolescents.
Duloxetine	Cymbalta	2/4/05 & 5/5/06	N	Lack of data re safety and efficacy in children for psychiatric indications.
Duloxetine	Cymbalta	05/07/2010	N	Only 1 Lilly sponsored study completed. Additional studies in pipeline. Deny approval until efficacy data is available.
Felbamate	Felbatol	10/08/2004	N	No indication for use as a psychotropic medication in children.
Guanfacine XR	Intuniv	10/09/2009	N	Pending further data once drug is actually available.
Guanfacine XR	Intuniv	02/05/2010	Y	Safety and efficacy data now available. Reviewed and approved.
Herbals/Nutritional Suppl	Herbals/Nutritional Suppl	04/01/2005	N	Not under perview of PMAC as they are not FDA regulated medications/possible inconsistency in formulations of the same product.
Iloperidone	Fanapt	03/05/2010	N	Lack of safety-efficacy data in children. Clinical trials not impressive. Need for careful titration is a concern. QTC interval is a concern.
Melatonin	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.
Metoprolol	Lopressor	09/04/2009	N	Removed due to lack of safety data and experience with use in children and adolescents.
Molindone	Moban	12/04/2009	Y	Associated with weight loss vs. gain. To remain on the approved drug list.
Nefazodone	Serzone	08/05/2004	N	ADR profile: Liver toxicity.
Olanzapine	Zyprexa	02/05/2010	Y	On approved list but restricted to DCF MD review. Based on FDA required change in prescribing information relating to weight gain.
Oxcarbazepine	Trileptal	12/01/2006	N	Lack of data re efficacy in children for psychiatric indications.
Oxcarbazepine	Trileptal	5/1/2009, 5/7/2010	N	Lack of safety-efficacy data in children. No new data available since last review.
Paliperidone	Invega	09/04/2009	N	Lack of safety-efficacy data in children.
Paroxetine	Paxil	03/05/2004	N	Higher risk of suicide per FDA advisory.
Pemoline	Cylert	08/05/2004	N	Withdrawn from market
Pimozide	Orap	09/05/2008	N	ADR profile: EKG changes - QT prolongation.
Prazosin	Minipres	06/05/2009	N	Restricted with caution. Dosing and efficacy data in children not available.
Ramelteon	Rozerem	09/04/2009	N	Lack of safety-efficacy data in children. Data may be available Feb 2010.
Thioridazine	Mellaril	08/05/2004	N	ADR profile: EKG changes - QT prolongation.
Tiagabine	Gabitril	10/08/2004	N	Lack of data re safety and efficacy in children for psychiatric indications.
Topiramate	Topamax	12/01/2006	N	Lack of data re efficacy in children for psychiatric indications.
Venlafaxine	Effexor	03/05/2004	N	Higher risk of suicide per FDA advisory.