Atypical Antipsychotic Long Acting Injectables Prescribing Information Table A

Generic (Brand) Year approved	Indication	Dosing	Oral Overlap	Tmax	T _{1/2}	Injection Interval	Pros & Cons
Aripiprazole monohydrate Abilify Asimtufii® 2023	Schizophrenia Bipolar I	720–960 mg every 8 weeks	Yes 14 days	1 - 49 days post- multiple gluteal 960 mg administrations	?	8 weeks	Pros Low risk of metabolic & endocrine AEs Aristada can be started using Initio
Aripiprazole lauroxil Aristada Initio® 2018	Schizophrenia	675 mg IM once + 30 mg aripiprazole PO once + one Aristada IM inj within 10 days	Yes (aripiprazole 30 mg PO once)	16 - 35 days (median 27 days)	15 - 18 days	Once	 675 mg IM + 30 mg oral dose instead of 3 weeks oral bridge (+ IM maintenance dose) 4 week, 6 week, 8 week and 2 months IM option
Aripiprazole lauroxil Aristada® 2015	Schizophrenia	441, 662, 882 mg IM once monthly, or 882 mg Q6-weeks or 1064 mg Q2-months	Yes 21 days	41 days (single dose) 24.4 - 35.2 days (repeated dosing)	53.9 - 57.2 days	4 weeks (all doses) 6 weeks (882 mg) 8 weeks (1064 mg)	 Rates of akathisia are comparable to D2 antagonist antipsychotic LAIs Abilify Maintena 200 mg & 160 mg dose can be obtained from 300 mg or 400 mg vials Cons A subset of clients may need a D2
Aripiprazole Abilify Maintena® 2013	Schizophrenia Bipolar I	300 or 400 mg IM once monthly	Yes 14 days	(gluteal) 4 days	29.9 days (300 mg) 46.5 days (400 mg)	4 weeks	 antagonist for optimal positive symptom control Abilify Asimtufii[®] and Maintena 1M require 2 weeks of oral overlap
Olanzapine Zyprexa Relprevv® 2009	Schizophrenia	150 or 210 mg IM Q-2 weeks 300 or 405 mg IM Q-4 weeks	No	7 days	30 days	2 to 4 weeks	Pros Olanzapine's small efficacy edge for some clts, Can be loaded, max dose equals 20 mg/day PO olanzapine Cons Metabolic AEs, post-injection syndrome causing delirium/sedation requires 3-hour observation

Generic (Brand) Year approved	Indication	Dosing	Oral Overlap	Tmax	T 1/2	Injection Interval	Pros & Cons
Paliperidone palmitate Invega Hafyera® 2021	Schizophrenia	1,092 mg or 1,560 mg once 6-monthly after treatment with monthly paliperidone for at least 4 months or 3-month paliperidone LAI for at least one 3-month cycle	No	148 - 159 days (gluteal)	29 - 32 days	6 months	Pros Can be loaded Few drug-drug interactions (renal excretion) Max dose corresponds to 6 mg/day oral
Paliperidone palmitate Invega Sustenna® 2009	Schizophrenia Schizoaffective Disorder	 Initiation: 234 mg followed by 156 mg IM (deltoid) one week later 39 mg, 78 mg,117 mg, 156 mg or 234 mg IM once monthly 	No	13 days	25 - 49 days	4 weeks	risperidone Offers 3-month & 6-month options for clts on Paliperidone Palmitate 1 month for at least 4 months Cons Metabolic side effects
Paliperidone palmitate Invega Trinza® 2015	Schizophrenia	273 mg, 410 mg, 546 mg, or 819 mg IM Q3-months after treatment with once monthly Invega Sustenna for at least 4 months (3.5 x the last Sustenna dose)	No	84 - 95 days (deltoid) 118 - 139 days (gluteal)	30 - 33 days	12 weeks	 Metabolic side effects Risk of hyperprolactinemia
Risperidone Perseris® 2018	Schizophrenia	90 mg or 120 mg SC once monthly	No	1st peak 4 to 6 hours (initial drug release d/t depot formation process). 2nd peak 10 to 14 days post-dose (slow release from the depot)	9-11 days	4 weeks	Pros Well established (risperidone approved in 1993) Subcutaneous LAIs eliminate the need for oral overlap Perseris and Uzedy can be administered in the upper arm
Risperidone Risperdal Consta® 2003	Schizophrenia Bipolar I	12.5 mg, 25 mg, 37.5 mg, or 50 mg IM Q-2 weeks	Yes, 21 days after initial inj or any change in dose	21 days	3 -6 days	2 weeks	 4 week & 8 week SQ inj option Uzedy dose range corresponds to 2, 3, 4, and 5 mg/day oral risperidone Cons
Risperidone Rykindo 2023	Schizophrenia Bipolar I	25 mg to 50 mg IM every 2 weeks	Yes (7 days)	14 days (25 mg) 17 days (50 mg)	3 to 6 days	2 weeks	 Metabolic & endocrine AEs Risperdal Consta require biweekly injections, 21 days oral overlap and
Risperidone Uzedy® 2023	Schizophrenia	Convert from PO to SQ: 2mg/day to 50mg monthly or 100mg bimonthly; 3mg/day to 75mg monthly or 150mg bimonthly; 4mg/day to 100mg monthly or 200mg bimonthly; 5mg/day to 125mg monthly or 250mg bimonthly	No	8 to 14 days	14 - 22 days	4 - 8 weeks	unfavorable PK • Perseris requires extensive mixing and comes in 90mg and 120mg doses, equivalent to 3mg/day and 4mg/day of oral risperidone respectively. Not suitable for doses outside 3-4mg/day range

Administration Information and Cost Table B

Generic Brand	Dosage Form/Strength	Requires Adding Diluent/ inj volume	Injection Type/Sites Needle gauge & Length	Refrigerated	Administration/Comments	Cost per 12 months *
Aripiprazolo monohydrat Abilify Asimtufii®		No 3.2 mL (960 mg) 2.4 mL (720 mg)	IM Gluteal 22G 1.5-inch or 21G 2-inch	No	 Tap 10 times, shake syringe vigorously for at least 10 seconds until the medication is uniform For non-obese patients, use a 22-gauge, 1.5-inch needle. For obese patients, use a 21-gauge, 2-inch needle 	Up to \$32,631
Aripiprazolo lauroxil Aristada Initio	injectable suspension	No 2.4 mL	IM Deltoid or Gluteal 21G 1-inch 20G 1.5-inch or 2-inch	No	 Tap & shake syringe vigorously for at least 30 seconds prior to use Aristada Initio is not interchangeable with Aristada (different PK profiles) Avoid use in known CYP2D6 poor Metabolizers 	
Aripiprazolo lauroxil Aristada	Prefilled syringe 441 mg, 662 mg, 882 mg, 1064 mg	No 3.9 mL (1064 mg) 3.2 mL (882 mg) 2.4 mL (662 mg) 1.6 mL (441 mg)	IM Deltoid (441 mg only) Gluteal (all doses) 21G 1-inch 20G 1.5-inch or 2-inch	No	 Tap 10 times, shake syringe vigorously for at least 30 seconds prior to use Inject over <10 seconds into deltoid or gluteal muscle (441 mg), gluteal only (662 or 882 mg) Use longer needles for larger amount of subcutaneous tissue overlaying the muscle 	Up to \$35,988
Aripiprazolo Abilify Maintena	1) 300 mg & 400 mg vials 2) 300 mg & 400 mg pre-filled dual chamber syringe	Yes, dual- chamber syringe also available 0.8 mL (160 mg) 1 mL (200 mg) 1.5 mL (300 mg) 2 mL (400 mg)	IM Deltoid or Gluteal 21G 2-inch, 22G 1.5-inch or 23G 1-inch	No	 Shake syringe vigorously for 20 seconds, shake vials for 30 sec. Inject <u>slowly</u> into deltoid or gluteal muscle (300 or 400 mg) adjust dose for strong CYP2D6 or CYP3A4 inhibitors; avoid use with strong CYP3A4 inducers 	Up to \$32,631
Olanzapine Pamoate Zyprexa Relprevv®	ER powder for suspension Vial Kits - 210 mg, 300 mg, 405 mg	No Range: 1.0 mL (150 mg) to 2.7 mL (405 mg [150mg/mL]	IM Gluteal 19G, 1.5-inch needle	No	Reconstituted suspension may be stored at room temperature and used within 24 hours. Shake vigorously to resuspend prior to use	Up to \$27,294

Generic Brand	Dosage Form/Strength	Requires Adding Diluent/ inj volume	Injection Type/Sites Needle gauge & Length	Refrigerated	Administration/Comments	Cost per 12 months *
Paliperidone palmitate Invega Halfyera®	Injectable suspension 1092 mg, 1560 mg	No 3.5 mL: 1092 mg 5 mL: 1560 mg	IM Gluteal 20G, 1.5-inch	No	 Shake syringe VERY FAST for at least 15 seconds, rest briefly & shake again for 15 seconds Administer within 5 minutes using the needles provided in the kit Inject slowly (~30 seconds) as a single injection deep into the gluteal muscle 	Up to \$39,833
Paliperidone palmitate Invega Sustenna®	Injectable suspension 39 mg, 78 mg, 117 mg, 156 mg, 234 mg	No Range: 0.25 mL (39 mg) to 1.5 mL (234 mg) [156 mg/mL]	IM Load: Deltoid only Maintenance: Deltoid or gluteal 22G, 1.5-inch 23G, 1-inch	No	Shake syringe vigorously for at least 10 seconds and select appropriate needle For deltoid inj, use 1-inch 23G needle for pts < 90 kg or 1½-inch 22G needle for pts ≥ 90 kg For gluteal inj, use 1½-inch 22G needle regardless of weight	Up to \$40,177
Paliperidone palmitate Invega Trinza®	Injectable suspension 273 mg, 410 mg, 546 mg, 819 mg	No Range 0.9 mL (273 mg) to 2.6 mL (819 mg) [312 mg/mL]	IM Deltoid or gluteal 22G, 1 or 1.5-inch	No	 Shake syringe vigorously for at least 15 seconds within 5 minutes prior to use Administer using only the needles provided in the kit 	Up to \$40,177
Risperidone Perseris®	Syringe kits: 90mg, 120 mg	Yes 0.6 mL (90 mg) 0.8 mL (120 mg)	Subcutaneous Abdomen or back of the upper arm 18G, 5/8-inch	Yes	 Constitute by coupling the liquid & powder syringes & passing the contents back & forth between the syringes. Incorrectly mixed medication could result in incorrect dosage Administer using the prepackaged syringe 	Up to \$33,130
Risperidone Risperdal Consta®	Vial kits: 12.5 mg, 25 mg, 37.5 mg, 50 mg	Yes ~ 2 mL	IM Deltoid or gluteal 20G, 2-inch 21G, 1-inch	Yes	Administer deep IM injection into deltoid or upper outer gluteal muscle using the provided needle. Alternate between both arms or buttocks	Up to \$28,150
Risperidone Rykindo [®]	Kit with vial & prefilled diluent in a syringe 12.5mg, 25mg, 37.5mg & 50mg	Yes ~ 2 mL	IM Gluteal 20G, 2-inch	Yes	Let kit reach room temperature for at least 30 minutes before use. Shake vigorously for at least 30 seconds after injecting diluent for uniform suspension. Resuspend by shaking vigorously for 20 to 30 seconds just before injection	Not available
Risperidone Uzedy®	Suspension Prefilled Syringe 50 mg, 75 mg, 100 mg, 125 mg, 150 mg, 200 mg, 250 mg	No Range: 0.14 mL (50 mg) to 0.7 mL (250 mg)	Subcutaneous Abdomen or upper arm 21G, 5/8-inch	Yes	Administer by SQ injection in the abdomen or upper arm by a healthcare professional Let the injection reach room temperature for at least 30 minutes before use Therapeutic concentrations attained within 6 to 24 hours after the first injection	Up to \$36,960

^{*}RxNova accessed 6/8/2023 for FDB WAC pricing

Formulary status

BHRS Indigent and CareAdvantage (HPSM) effective July 1, 2023

<u>PA requirement removed for:</u> Abilify Maintena, Aristada ER, Aristada Initio, Invega Sustenna, Invega Trinza, Perseris, Risperdal Consta <u>PA requirement remains for:</u> Invega Hafyera, Zyprexa Zelprev

State MediCal through DHCS/Magellan

PA required for all antipsychotic LAIs

Formulary Recommendation Abilify Asimtufii

Add to BHRS, CareAdvantage, and HealthWorx formulary with PA criteria:

Indication—FDA approved diagnoses

Age—Adults

Documentation—

Patient has tried and failed oral antipsychotic therapy Or

Transferred from hospital/facility/another provider stabilized on this medication

Quantity Limit --

#1/60DS for 760mg and 960mg

Formulary Recommendation For Uzedy

Add to BHRS, CareAdvantage, and HealthWorx formulary with PA criteria:

Indication—FDA approved diagnoses

Documentation—

Patient has tried and failed oral antipsychotic therapy Or

 $Transferred\ from\ hospital/facility/another\ provider\ stabilized\ on\ this\ medication$

Quantity Limit --

#1/30DS for 50mg, 75mg, 100mg, 125mg

#1/60DS for 150mg, 200mg, 250mg