



# Atypical Antipsychotics- Extended Maintenance Agents Step Therapy with Quantity Limit Program Summary

This program applies to FlexRx Open, FocusRx, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

## POLICY REVIEW CYCLE

**Effective Date**                      **Date of Origin**  
 07-01-2024

## FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Abilify Asimtufii®  (aripiprazole)  IM injection	Treatment of schizophrenia in adults  As maintenance monotherapy treatment of bipolar I disorder in adult		13
Abilify Maintena®  (aripiprazole)  IM injection	Treatment of schizophrenia in adults  Main monotherapy treatment of bipolar I disorder in adults		1
Aristada Initio®  (aripiprazole)  IM injection	In combination with oral aripiprazole, is indicated for the initiation of Aristada when used for the treatment of schizophrenia in adults		3
Aristada®  (aripiprazole)  IM injection	Treatment of schizophrenia in adults		2
Invega Hafyera™  (paliperidone)  IM injection	Treatment of schizophrenia in adults after they have been adequately treated with:  <ul style="list-style-type: none"> <li>A once-a-month paliperidone palmitate extended-release injectable suspension (e.g., Invega Sustenna) for at least four months</li> </ul> OR		12

Agent(s)	FDA Indication(s)	Notes	Ref#
	<ul style="list-style-type: none"> <li>An every-three-month paliperidone palmitate extended-release injectable suspension (e.g., Invega Trinza) for at least one three-month cycle</li> </ul>		
Invega Sustenna®  (paliperidone)  IM injection	Treatment of schizophrenia in adults  Treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants		4
Invega Trinza®  (paliperidone)  IM injection	Treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna (1-month paliperidone palmitate extended-release injectable suspension) for at least four months		5
Perseris®  (risperidone)  SC injection	Treatment of schizophrenia in adults		6
Risperdal Consta®  (risperidone)  IM injection	Treatment of schizophrenia  As monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder		7
Rykindo®  (risperidone ER)  IM injection	Treatment of schizophrenia in adults  As monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults.		15
Uzedy®  (risperidone ER)  SC injection	Treatment of schizophrenia in adults		14
Zyprexa® Relprevv™  (olanzapine)  IM injection	Treatment of schizophrenia		8

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

## CLINICAL RATIONALE

Safety	The Atypical Antipsychotics – Extended Maintenance Agents carry a black box warning for increased mortality in elderly patients with dementia-related psychosis. The warning states that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. These agents not approved for
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	<p>the treatment of patients with dementia-related psychosis. In addition to the FDA black box warning, Zyprexa Relprevv carries a black box warning concerning post-injection delirium/sedation syndrome. The warning states that patients are at risk for severe sedation (including coma) and/or delirium after each injection and must be observed for at least 3 hours in a registered facility with ready access to emergency response services. Because of this risk, Zyprexa Relprevv is available only through a restricted distribution program called Zyprexa Relprevv Patient Care Program and requires, prescriber, healthcare facility, patient, and pharmacy enrollment.(1-15)</p> <p>Antipsychotic drug therapy generally is reserved for patients who have severe symptoms or when associated agitation, combativeness, or violent behavior puts the patient or others in danger. Current evidence indicates that the atypical antipsychotics can provide modest improvement in behavioral manifestations; some evidence suggests that efficacy may be better for psychosis than for other manifestations. Antipsychotic efficacy appears to be similar among available agents and therefore the choice of agent should be based on adverse effect profile and other patient considerations; to minimize adverse effects, the lowest possible effective dose should be used.(1-8,12-15)</p>
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## REFERENCES

Number	Reference
1	Abilify Maintena prescribing information. Otsuka America Pharmaceutical, Inc. February 2020.
2	Aristada prescribing information. Alkermes, Inc. December 2023.
3	Aristada Initio prescribing information. Alkermes, Inc. December 2023.
4	Invega Sustenna prescribing information. Janssen Pharmaceuticals, Inc. July 2022.
5	Invega Trinza prescribing information. Janssen Pharmaceuticals, Inc. August 2021.
6	Perseris prescribing information. Indivior, Inc. August 2022.
7	Risperdal Consta prescribing information. Janssen Pharmaceuticals, Inc. February 2021.
8	Zyprexa Relprevv prescribing information. Eli Lilly and Company. October 2023.
9	Rabins, Peter, MD, MPH, et al. Practice Guideline for the Treatment of Patients with Alzheimer’s Disease and Other Dementias. Second Edition. American Psychiatric Association. Available at: <a href="https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/alzheimers.pdf">https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/alzheimers.pdf</a> .
10	Rabins PV, Rovner BW et. al. Guideline Watch (2014) Practice Guideline for the Treatment of Patients with Alzheimer’s Disease and Other Dementias. American Psychiatric Association. Available: <a href="https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/alzheimerwatch.pdf">https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/alzheimerwatch.pdf</a> .
11	Reus, Victor, MD, et al. Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia. First Edition. May 2016. American Psychiatric Association. Available at: <a href="https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890426807">https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890426807</a> .
12	Invega Hafyera prescribing information. Janssen Pharmaceuticals, Inc. August 2021.
13	Abilify Asimtufii prescribing information. Otsuka Pharmaceutical Co., Ltd. August 2023.
14	Uzedy prescribing information. Teva Neuroscience, Inc. May 2023.
15	Rykindo prescribing information. Shandong Luye Pharmaceutical Co, Ltd. January 2023.

## POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Abilify asimtufii ; Abilify maintena	aripiprazole im er susp prefilled syringe ; aripiprazole im for er susp prefilled syringe	300 MG ; 400 MG ; 720 MG/2.4ML ; 960 MG/3.2ML	M ; N ; O ; Y	N		
Abilify maintena	aripiprazole im for extended release susp	300 MG ; 400 MG	M ; N ; O ; Y	N		
Aristada ; Aristada initio	aripiprazole lauroxil im er susp prefilled syr	1064 MG/3.9ML ; 441 MG/1.6ML ; 662 MG/2.4ML ; 675 MG/2.4ML ; 882 MG/3.2ML	M ; N ; O ; Y	N		
Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1092 MG/3.5ML	M ; N ; O ; Y	N		
Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1560 MG/5ML	M ; N ; O ; Y	N		
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 117 MG/0.75ML	117 MG/0.75ML	M ; N ; O ; Y	N		
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 156 MG/ML	156 MG/ML	M ; N ; O ; Y	N		
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 234 MG/1.5ML	234 MG/1.5ML	M ; N ; O ; Y	N		
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 39 MG/0.25ML	39 MG/0.25ML	M ; N ; O ; Y	N		
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 78 MG/0.5ML	78 MG/0.5ML	M ; N ; O ; Y	N		
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 273 MG/0.875ML	273 MG/0.88ML	M ; N ; O ; Y	N		
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 410 MG/1.315ML	410 MG/1.32ML	M ; N ; O ; Y	N		
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 546 MG/1.75ML	546 MG/1.75ML	M ; N ; O ; Y	N		
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 819 MG/2.625ML	819 MG/2.63ML	M ; N ; O ; Y	N		
Perseris	risperidone subcutaneous for er susp prefilled syr	120 MG ; 90 MG	M ; N ; O ; Y	N		
Risperdal consta	risperidone microspheres for im extended rel susp	12.5 MG ; 25 MG ; 37.5 MG ; 50 MG	M ; N ; O ; Y	O ; Y		
Rykindo	risperidone for im extended release suspension	25 MG ; 37.5 MG ; 50 MG	M ; N ; O ; Y	N		
Uzedy	risperidone subcutaneous er susp pref syr	100 MG/0.28ML ; 125 MG/0.35ML ; 150 MG/0.42ML ; 200 MG/0.56ML ; 250 MG/0.7ML ; 50 MG/0.14ML ; 75 MG/0.21ML	M ; N ; O ; Y	N		
Zyprexa relprevv	olanzapine pamoate for extended rel im susp	210 MG ; 300 MG ; 405 MG	M ; N ; O ; Y	N		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Abilify asimtufii	aripiprazole im er susp prefilled syringe	720 MG/2.4 ML	1	Syringe	56	DAYS			
Abilify asimtufii	aripiprazole im er susp prefilled syringe	960 MG/3.2 ML	1	Syringes	56	DAYS			
Abilify asimtufii ; Abilify maintena	aripiprazole im er susp prefilled syringe ; aripiprazole im for er susp prefilled syringe	300 MG ; 400 MG ; 720 MG/2.4 ML ; 960 MG/3.2 ML	1	Syringe	28	DAYS			
Abilify maintena	Aripiprazole IM For ER Susp Prefilled Syringe 300 MG	300 MG	1	Syringe	28	DAYS			
Abilify maintena	Aripiprazole IM For ER Susp Prefilled Syringe 400 MG	400 MG	1	Syringe	28	DAYS			
Abilify maintena	aripiprazole im for extended release susp	300 MG ; 400 MG	1	Vial	28	DAYS			
Abilify maintena	Aripiprazole IM For Extended Release Susp 300 MG	300 MG	1	Vial	28	DAYS			
Abilify maintena	Aripiprazole IM For Extended Release Susp 400 MG	400 MG	1	Vial	28	DAYS			
Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 1064 MG/3.9ML	1064 MG/3.9 ML	1	Syringe	56	DAYS			
Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 441 MG/1.6ML	441 MG/1.6 ML	1	Syringe	28	DAYS			
Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 662 MG/2.4ML	662 MG/2.4 ML	1	Syringe	28	DAYS			
Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 882 MG/3.2ML	882 MG/3.2 ML	1	Syringe	28	DAYS			
Aristada initio	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 675 MG/2.4ML	675 MG/2.4 ML	1	Kit	180	DAYS			
Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1092 MG/3.5 ML	1	Syringe	180	DAYS			
Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1560 MG/5ML	1	Syringe	180	DAYS			
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 117 MG/0.75ML	117 MG/0.75 ML	1	Kit	28	DAYS			
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 156 MG/ML	156 MG/ML	1	Kit	28	DAYS			
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 234 MG/1.5ML	234 MG/1.5 ML	1	Kit	28	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 39 MG/0.25ML	39 MG/0.25 ML	1	Kit	28	DAYS			
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 78 MG/0.5ML	78 MG/0.5 ML	1	Kit	28	DAYS			
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 273 MG/0.875ML	273 MG/0.88 ML	1	Syringe	84	DAYS			
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 410 MG/1.315ML	410 MG/1.32 ML	1	Syringe	84	DAYS			
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 546 MG/1.75ML	546 MG/1.75 ML	1	Syringe	84	DAYS			
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 819 MG/2.625ML	819 MG/2.63 ML	1	Syringe	84	DAYS			
Perseris	risperidone subcutaneous for er susp prefilled syr	120 MG ; 90 MG	1	Kit	30	DAYS			
Perseris	Risperidone Subcutaneous For ER Susp Prefilled Syr 120 MG	120 MG	1	Kit	28	DAYS			
Perseris	Risperidone Subcutaneous For ER Susp Prefilled Syr 90 MG	90 MG	1	Kit	28	DAYS			
Risperdal consta	risperidone microspheres for im extended rel susp	12.5 MG ; 25 MG ; 37.5 MG ; 50 MG	2	Vials	28	DAYS			
Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 12.5 MG	12.5 MG	2	Vials	28	DAYS			
Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 25 MG	25 MG	2	Vials	28	DAYS			
Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 37.5 MG	37.5 MG	2	Vials	28	DAYS			
Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 50 MG	50 MG	2	Vials	28	DAYS			
Rykindo	risperidone for im extended release suspension	25 MG	2	Vials	28	DAYS			
Rykindo	risperidone for im extended release suspension	37.5 MG	2	Vials	28	DAYS			
Rykindo	risperidone for im extended release suspension	50 MG	2	Vials	28	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Uzedy	risperidone subcutaneous er susp pref syr	50 MG/0.14 ML	1	Syringe	28	DAYS			
Uzedy	risperidone subcutaneous er susp pref syr	75 MG/0.21 ML	1	Syringe	28	DAYS			
Uzedy	risperidone subcutaneous er susp pref syr	100 MG/0.28 ML	1	Syringe	28	DAYS			
Uzedy	risperidone subcutaneous er susp pref syr	125 MG/0.35 ML	1	Syringe	28	DAYS			
Uzedy	risperidone subcutaneous er susp pref syr	150 MG/0.42 ML	1	Syringe	56	DAYS			
Uzedy	risperidone subcutaneous er susp pref syr	200 MG/0.56 ML	1	Syringe	56	DAYS			
Uzedy	risperidone subcutaneous er susp pref syr	250 MG/0.7 ML	1	Syringe	56	DAYS			
Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 210 MG (Base Eq)	210 MG	2	Vials	28	DAYS			
Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 300 MG (Base Eq)	300 MG	2	Vials	28	DAYS			
Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 405 MG (Base Eq)	405 MG	1	Vial	28	DAYS			

## CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Abilify asimtufii ; Abilify maintena	aripiprazole im er susp prefilled syringe ; aripiprazole im for er susp prefilled syringe	300 MG ; 400 MG ; 720 MG/2.4ML ; 960 MG/3.2ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abilify maintena	aripiprazole im for extended release susp	300 MG ; 400 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Aristada ; Aristada initio	aripiprazole lauroxil im er susp prefilled syr	1064 MG/3.9ML ; 441 MG/1.6ML ; 662 MG/2.4ML ; 675 MG/2.4ML ; 882 MG/3.2ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1560 MG/5ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1092 MG/3.5ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 117 MG/0.75ML	117 MG/0.75ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 156 MG/ML	156 MG/ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 234 MG/1.5ML	234 MG/1.5ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 39 MG/0.25ML	39 MG/0.25ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 78 MG/0.5ML	78 MG/0.5ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 273 MG/0.875ML	273 MG/0.88ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 410 MG/1.315ML	410 MG/1.32ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 546 MG/1.75ML	546 MG/1.75ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 819 MG/2.625ML	819 MG/2.63ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Perseris	risperidone subcutaneous for er susp prefilled syr	120 MG ; 90 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Risperdal consta	risperidone microspheres for im extended rel susp	12.5 MG ; 25 MG ; 37.5 MG ; 50 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Rykindo	risperidone for im extended release suspension	25 MG ; 37.5 MG ; 50 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Uzedy	risperidone subcutaneous er susp pref syr	100 MG/0.28ML ; 125 MG/0.35ML ; 150 MG/0.42ML ; 200 MG/0.56ML ; 250 MG/0.7ML ; 50 MG/0.14ML ; 75 MG/0.21ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zyprexa relprevv	olanzapine pamoate for extended rel im susp	210 MG ; 300 MG ; 405 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx



## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Abilify asimtufii	aripiprazole im er susp prefilled syringe	960 MG/3.2ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abilify asimtufii	aripiprazole im er susp prefilled syringe	720 MG/2.4ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abilify asimtufii ; Abilify maintena	aripiprazole im er susp prefilled syringe ; aripiprazole im for er susp prefilled syringe	300 MG ; 400 MG ; 720 MG/2.4ML ; 960 MG/3.2ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abilify maintena	Aripiprazole IM For ER Susp Prefilled Syringe 300 MG	300 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abilify maintena	Aripiprazole IM For ER Susp Prefilled Syringe 400 MG	400 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abilify maintena	aripiprazole im for extended release susp	300 MG ; 400 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abilify maintena	Aripiprazole IM For Extended Release Susp 300 MG	300 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abilify maintena	Aripiprazole IM For Extended Release Susp 400 MG	400 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 1064 MG/3.9ML	1064 MG/3.9ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 441 MG/1.6ML	441 MG/1.6ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 662 MG/2.4ML	662 MG/2.4ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 882 MG/3.2ML	882 MG/3.2ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Aristada initio	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 675 MG/2.4ML	675 MG/2.4ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1560 MG/5ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1092 MG/3.5ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 117 MG/0.75ML	117 MG/0.75ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 156 MG/ML	156 MG/ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 234 MG/1.5ML	234 MG/1.5ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 39 MG/0.25ML	39 MG/0.25ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 78 MG/0.5ML	78 MG/0.5ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 273 MG/0.875ML	273 MG/0.875ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 410 MG/1.315ML	410 MG/1.315ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 546 MG/1.75ML	546 MG/1.75ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 819 MG/2.625ML	819 MG/2.625ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Perseris	risperidone subcutaneous for er susp prefilled syr	120 MG ; 90 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Perseris	Risperidone Subcutaneous For ER Susp Prefilled Syr 120 MG	120 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Perseris	Risperidone Subcutaneous For ER Susp Prefilled Syr 90 MG	90 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Risperdal consta	risperidone microspheres for im extended rel susp	12.5 MG ; 25 MG ; 37.5 MG ; 50 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 12.5 MG	12.5 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 25 MG	25 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 37.5 MG	37.5 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 50 MG	50 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Rykindo	risperidone for im extended release suspension	50 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Rykindo	risperidone for im extended release suspension	25 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Rykindo	risperidone for im extended release suspension	37.5 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Uzedy	risperidone subcutaneous er susp pref syr	125 MG/0.35ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Uzedy	risperidone subcutaneous er susp pref syr	50 MG/0.14ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Uzedy	risperidone subcutaneous er susp pref syr	200 MG/0.56ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Uzedy	risperidone subcutaneous er susp pref syr	100 MG/0.28ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Uzedy	risperidone subcutaneous er susp pref syr	150 MG/0.42ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Uzedy	risperidone subcutaneous er susp pref syr	250 MG/0.7ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Uzedy	risperidone subcutaneous er susp pref syr	75 MG/0.21ML	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 210 MG (Base Eq)	210 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 300 MG (Base Eq)	300 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 405 MG (Base Eq)	405 MG	FlexRx Open ; FocusRx ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

## STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval														
	<table border="1"> <thead> <tr> <th>TARGET AGENT(S)</th> <th>PREREQUISITE AGENT(S)</th> </tr> </thead> <tbody> <tr> <td> <b>Abilify Asimtufii</b> (aripiprazole)  <b>Abilify Maintena</b> (aripiprazole)  <b>Aristada</b> (aripiprazole)  <b>Aristada Initio</b> (aripiprazole) </td> <td> Any oral brand or generic:  Abilify  Abilify Mycite  aripiprazole ODT  aripiprazole solution  aripiprazole </td> </tr> <tr> <td><b>Invega Hafyera</b> (paliperidone)</td> <td>Invega Sustenna Invega Trinza</td> </tr> <tr> <td><b>Invega Sustenna</b> (paliperidone)</td> <td>Any oral brand or generic: Invega ER paliperidone ER</td> </tr> <tr> <td><b>Invega Trinza</b> (paliperidone)</td> <td>Invega Sustenna</td> </tr> <tr> <td> <b>Perseris</b> (risperidone)  <b>Risperdal Consta</b> (risperidone)*  <b>Rykindo</b> (risperidone ER)  <b>Uzedy</b> (risperidone ER) </td> <td> Any oral brand or generic:  Risperdal  Risperdal solution  risperidone  Risperidone ODT, risperidone ODT </td> </tr> <tr> <td><b>Zyprexa Relprevv</b> (olanzapine)</td> <td>Any oral brand or generic: olanzapine Zyprexa Zyprexa Zydis</td> </tr> </tbody> </table> <p>* - generic available; generic is a target</p> <p><b>Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>The patient is currently being treated with the requested agent within the past 180 days <b>OR</b></li> <li>The prescriber states the patient is currently being treated with the requested agent with the past 180 days AND is at risk if therapy is changed <b>OR</b></li> <li>The patient is currently being treated with the requested agent as indicated by ALL of the following: <ol style="list-style-type: none"> <li>A statement by the prescriber that the patient is currently taking the requested agent <b>AND</b></li> <li>A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent <b>AND</b></li> <li>The prescriber states that a change in therapy is expected to be ineffective or cause harm <b>OR</b></li> </ol> </li> <li>The patient's medication history includes prerequisite agent use, intolerance, or hypersensitivity <b>OR</b></li> <li>BOTH of the following: <ol style="list-style-type: none"> <li>The prescriber has stated that the patient has tried the prerequisite agent <b>AND</b></li> <li>The prerequisite agent was discontinued due to lack of effectiveness or an adverse event <b>OR</b></li> </ol> </li> <li>The patient has an FDA labeled contraindication to ALL prerequisite agents that is not expected to occur with the requested agent <b>OR</b></li> <li>The prescriber has provided documentation that ALL prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction,</li> </ol>	TARGET AGENT(S)	PREREQUISITE AGENT(S)	<b>Abilify Asimtufii</b> (aripiprazole) <b>Abilify Maintena</b> (aripiprazole) <b>Aristada</b> (aripiprazole) <b>Aristada Initio</b> (aripiprazole)	Any oral brand or generic: Abilify Abilify Mycite aripiprazole ODT aripiprazole solution aripiprazole	<b>Invega Hafyera</b> (paliperidone)	Invega Sustenna Invega Trinza	<b>Invega Sustenna</b> (paliperidone)	Any oral brand or generic: Invega ER paliperidone ER	<b>Invega Trinza</b> (paliperidone)	Invega Sustenna	<b>Perseris</b> (risperidone) <b>Risperdal Consta</b> (risperidone)* <b>Rykindo</b> (risperidone ER) <b>Uzedy</b> (risperidone ER)	Any oral brand or generic: Risperdal Risperdal solution risperidone Risperidone ODT, risperidone ODT	<b>Zyprexa Relprevv</b> (olanzapine)	Any oral brand or generic: olanzapine Zyprexa Zyprexa Zydis
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Module	Clinical Criteria for Approval
	<p>decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm</p> <p><b>Length of Approval:</b> 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Quantity limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested agent does not have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit <b>OR</b></li> </ol> </li> <li>C. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b> up to 12 months</p>