Self-Administered Oncology Agents Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

Program specific denial language for prerequisite step therapy component does not apply. Instead, supplemental program denial language will apply.

FDA APPROVED INDICATIONS[3-85]
Please reference individual agent product labeling.

CLINICAL RATIONALE
For the purposes of the Self-Administered Oncology Agents criteria, indications deemed appropriate are those approved in FDA labeling and/or supported by NCCN Drugs & Biologics compendia with a category 1, 2A, or 2B recommendation, AHFS, DrugDex with level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, or Clinical Pharmacology.

SAFETY[3-85]

Agent	Contraindications
Afinitor/Afinitor Disperz (everolimus)	Hypersensitivity to everolimus, to other rapamycin derivatives
Alecensa (alectinib)	None
Alunbrig (brigatinib)	None
Balversa (erdafitinib)	None
Bosulif (bosutinib)	Hypersensitivity to bosutinib
Braftovi (encorafenib)	None
Cabometyx (cabozantinib)	None
Calquence (acalabrutinib)	None
Caprelsa (vandetanib)	Congenital long QT syndrome
Cometriq (cabozantinib)	None
Copiktra (duvelisib)	None
Cotellic (cobimetinib)	None
Daurismo (glasdegib)	None
Erivedge (vismodegib)	None
Erleada (apalutamide)	Pregnancy
Farydak (panobinostat)	None
Gilotrif (afatinib)	None
Gleevec (imatinib)	None

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

Agent	Contraindications
Hexalen (altretamine)	Hypersensitivity to altretamine, preexisting severe bone marrow depression, severe neurological toxicity
Hycamtin (topotecan)	Severe hypersensitivity to topotecan
Ibrance (palbociclib)	None
Iclusig (ponatinib)	None
Idhifa (enasidenib)	None
Imbruvica (ibrutinib)	None
Inlyta (axitinib)	None
Inrebic (fedratinib)	None
Iressa (gefitinib)	None
Jakafi (ruxolitinib)	None
Kisqali (ribociclib)	None
Kisqali Femara Pack (ribociclib and letrozole co-packaged)	Hypersensitivity to letrozole, or any excipients of Femara
Lenvima (lenvatinib)	None
Lonsurf (trifluridine/tipiracil)	None
Lorbrena (lorlatinib)	Concomitant use with a strong CYP3A inducer, due to potential for serious hepatotoxicity
Lynparza (olaparib) capsules	None
Lynparza (olaparib) tablets	None
Lysodren (mitotane)	None
Matulane (procarbazine)	Known hypersensitivity to procarbazine, inadequate marrow reserve
Mekinist (trametinib)	None
Mektovi (binimetinib)	None
Nerlynx (neratinib)	None
Nexavar (sorafenib)	Known severe hypersensitivity to sorafenib or its components, use in combination with carboplatin and paclitaxel in patients with squamous cell lung cancer
Ninlaro (ixazomib)	None
Nubeqa (darolutamide)	None
Odomzo (sonidegib)	None
Piqray (alpelisib)	Severe hypersensitivity to Piqray or to any of its components
Pomalyst (pomalidomide)	Pregnancy
Revlimid (lenalidomide)	Pregnancy, severe hypersensitivity to lenalidomide
Rozlytrek (entrectinib)	None
Rubraca (rucaparib)	None
Rydapt (midostaurin)	Hypersensitivity to midostaurin or any of the excipients
Sprycel (dasatinib)	None
Stivarga (regorafenib)	None

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

Agent	Contraindications
Sutent (sunitinib)	None
Sylatron (peginterferon alfa-2b)	Autoimmune hepatitis, hepatic decompensation (Child-Pugh score >6, Class B and C), hypersensitivity to peginterferon alfa-2b or interferon alfa-2b
Tafinlar (dabrafenib)	None
Tagrisso (osimertinib)	None
Talzenna (talazoparib)	None
Tarceva (erlotinib)	None
Targretin (bexarotene)	Pregnancy; known serious hypersensitivity to bexarotene or other components of the product
Tasigna (nilotinib)	Hypokalemia, hypomagnesemia, long QT syndrome
Temodar (temozolomide)	Hypersensitivity to dacarbazine (DTIC) or Temodar components
Thalomid (thalidomide)	Pregnancy, hypersensitivity to thalidomide or its components
Tibsovo (ivosidenib)	None
Tretinoin (oral)	known hypersensitivity to tretinoin, any of its components, or other retinoids; sensitivity to parabens
Turalio (pexidartinib)	None
Tykerb (lapatinib)	Known hypersensitivity to lapatinib or its components
Venclexta (venetoclax)	Concomitant use with strong CYP3A inhibitors at initiation and during ramp-up phase in patients with CLL/SLL
Verzenio (abemaciclib)	None
Vitrakvi (larotrectinib)	None
Vizimpro (dacomitinib)	None
Votrient (pazopanib)	None
Xalkori (crizotinib)	None
Xeloda (capecitabine)	Severe renal failure, hypersensitivity to capecitabine or any of its components, hypersensitivity to 5-fluorouracil
Xospata (gilteritinib)	Hypersensitivity to gilteritinib or any of the excipients
Xpovio (selinexor)	None
Xtandi (enzalutamide)	Pregnancy
Yonsa (abiraterone acetate)	Pregnancy
Zejula (niraparib)	None
Zelboraf (vemurafenib)	None
Zolinza (vorinostat)	None
Zydelig (idelalisib)	History of serious allergic reactions including anaphylaxis and toxic epidermal necrolysis
Zykadia (ceritinib)	None
Zytiga (abiraterone)	None

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

REFERENCES

1. Sacco Jj, Botten J, Macbeth F, et al. The average body surface area of adult cancer patients in the UK: A multicentre retrospective study. *PLoS ONE* 5(1):e8933. Doi:10.1371/journal.pone.0008933.
2. Verbraecken J et al. Body surface area in normal-weight, overweight, and obese adults. A Comparison study. *Metabolism Clinical and Experimental* 2006;55:515-524.
3. Afinitor/Afinitor Disperz prescribing information. Novartis. April 2018.
4. Alecensa prescribing information. Genentech. June 2018.
5. Alunbrig prescribing information. Ariad Pharmaceuticals Inc. December 2018.
6. Balversa prescribing information. Janssen Pharmaceutical Companies. April 2019.
7. Bosulif prescribing information. Pfizer Inc. October 2018.
8. Braftovi prescribing information. Array BioPharma Inc. May 2019.
9. Cabometyx prescribing information. Exelixis Inc. January 2019.
10. Calquence prescribing information. AstraZeneca. November 2017.
11. Caprelsa prescribing information. AstraZeneca Pharmaceuticals. December 2018.
12. Cometriq prescribing information. Exelixis, Inc. January 2018.
13. Copiktra prescribing information. Verastem, Inc. September 2018.
14. Cotellic prescribing information. Genentech. January 2018.
15. Daurismo prescribing information. Pfizer Inc. November 2018.
16. Erivedge prescribing information. Genentech. February 2019.
17. Erleada prescribing information. Janssen Ortho LLC. February 2018.
18. Farydak prescribing information. Novartis. December 2017.
19. Gilotrif prescribing information. Boehringer Ingelheim Pharmaceuticals. January 2018.
20. Gleevec prescribing information. Novartis. July 2018.
21. Hexalen prescribing Information. MGI PHARMA, INC. June 2018.
22. Hycamtin prescribing Information. GSK. September 2018.
23. Ibrance prescribing information. Pfizer. April 2019.
24. Iclusig prescribing Information. ARIAD Pharmaceuticals. October 2018.
25. Idhifa prescribing information. Celgene. August 2017.
26. Imbruvica prescribing information. Pharmacyclics, Inc. January 2019.
27. Inlyta prescribing information. Pfizer. New York, NY. August 2018.
28. Inrebic prescribing information. Impact Biomedicines, Inc. August 2019.
29. Iressa prescribing information. AstraZeneca. August 2018.
30. Jakafi prescribing information. Incyte. May 2019.
31. Kisqali Femara Pack prescribing information. Novartis. July 2018.
32. Kisqali prescribing information. Novartis. February 2019.
33. Lenvima prescribing information. Eisai. December 2018.
34. Lonsurf prescribing information. Taiho Oncology. February 2019.
35. Lorbrena prescribing information. Pfizer Inc. November 2018.
36. Lynparza capsules prescribing information. AstraZeneca. September 2018.
37. Lynparza tablets prescribing information. AstraZeneca. December 2018.
38. Lysodren prescribing Information. E.R. Squibb & Sons, L.L.C. July 2018.
39. Matulane prescribing Information. Sigma-tau. August 2018.
40. Mekinist prescribing information. GlaxoSmithKline. July 2019.
41. Mektovi prescribing information. Array BioPharma Inc. January 2019.
42. Nerlynx prescribing information. Puma Biotech. July 2018.
43. Nexavar prescribing information. Bayer. December 2018.
44. Ninlaro prescribing information. Millennium. November 2016.
45. Nubeqa prescribing information. Bayer HealthCare Pharmaceuticals Inc. July 2019.
46. Odomzo prescribing information. Novartis. May 2019.
47. Piqray prescribing information. Novartis Pharmaceuticals Corp. May 2019.
48. Pomalyst prescribing information. Celgene Corporation. June 2018.
49. Revlimid prescribing information. Celgene Corporation. May 2019.

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

50. Rozlytrek prescribing information. Genentech USA, Inc. August 2019.
51. Rubraca prescribing information. Clovis Oncology. April 2018.
52. Rydapt prescribing information. Novartis. June 2018.
53. Sprycel prescribing information. E.R. Squibb & Sons, L.L.C. December 2018.
54. Stivarga prescribing information. Bayer Healthcare Pharmaceuticals. June 2018.
55. Sutent prescribing information. Pfizer. May 2019.
56. Sylatron prescribing information. Schering Corporation. December 2018.
57. Tafinlar prescribing information. GlaxoSmithKline. July 2019.
58. Tagrisso prescribing information. AstraZeneca. August 2018.
59. Talzenna prescribing information. Pfizer Inc. October 2018.
60. Tarceva prescribing information. Genentech. October 2016.
61. Targretin prescribing information. Valeant. October 2015.
62. Tasigna prescribing information. Novartis. July 2018.
63. Temodar prescribing Information. Merck Sharp & Dohme Corp. October 2017.
64. Thalomid prescribing information. Celgene Corporation. June 2019.
65. Tibsovo prescribing information. Agios Pharmaceuticals, Inc. May 2019.
66. Tretinoin prescribing information. Barr Laboratories, Inc. January 2018.
67. Turalio prescribing information. Daiichi Sankyo, Inc. August 2019.
68. Tykerb prescribing information. GSK. December 2018.
69. Venclexta prescribing information. AbbVie Inc. July 2019.
70. Verzenio prescribing information. Eli Lilly and Company. February 2018.
71. Vitrakvi prescribing information. Loxo Oncology, Inc. November 2018.
72. Vizimpro prescribing information. Pfizer Inc. September 2018.
73. Votrient prescribing information. GSK. May 2017.
74. Xalkori prescribing information. Pfizer. December 2018.
75. Xeloda prescribing information. Genentech, Inc. February 2019.
76. Xospata prescribing information. Astellas Pharma Inc. May 2019.
77. Xpovio prescribing information. Karyopharm Therapeutics Inc. July 2019.
78. Xtandi prescribing information. Astellas Pharma US, Inc. July 2018.
79. Yonsa prescribing information. Sun Pharmaceuticals Inc. June 2018.
80. Zejula prescribing information. Tesaro. February 2019.
81. Zelboraf prescribing information. Genentech, USA. December 2017.
82. Zolinza prescribing information. Merck Sharp & Dohme Corp. December 2018.
83. Zydelig prescribing information. Gilead Sciences, Inc. October 2018.
84. Zykadia prescribing information. Novartis Pharmaceuticals. March 2019.
85. Zytiga prescribing information. Janssen Biotech, Inc. June 2019.

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

Self-Administered Oncology Agents Prior Authorization with Quantity Limit

TARGET AGENTS

Afinitor® (everolimus)
Afinitor® Disperz (everolimus)
Alecensa® (alectinib)
Alunbrig™ (brigatinib)
Balversa™ (erdafitinib)
Bosulif® (bosutinib)
Braftovi® (encorafenib)
Cabometyx® (cabozantinib)
Calquence® (acalabrutinib)
Caprelsa® (vandetanib)
Cometriq® (cabozantinib)
Copiktra (duvelisib)
Cotellic® (cobimetinib)
Daurismo™ (glasdegib)
Erivedge® (vismodegib)
Erleada™ (apalutamide)
Farydak® (panobinostat)
Gilotrif® (afatinib)
[a]Gleevec® (imatinib)
Hexalen® (altretamine)
Hycamtin® (topotecan)
Ibrance® (palbociclib)
Iclusig® (ponatinib)
Idhifa® (enasidenib)
Inlyta® (axitinib)
Imbruvica® (ibrutinib)
Inrebic® (fedratinib)
Iressa® (gefitinib)
Jakafi® (ruxolitinib)
Kisqali® (ribociclib)
Kisqali® Femara® Pack (ribociclib and letrozole co-packaged)
Lenvima® (lenvatinib)
Lonsurf (trifluridine/tipiracil)
Lorbrena® (lorlatinib)
Lynparza® (olaparib) capsules
Lynparza® (olaparib) tablets
Lysodren® (mitotane)
Matulane® (procarbazine)
Mekinist® (trametinib)
Mektovi® (binimetinib)
Nerlynx (neratinib)
Nexavar (sorafenib)
Ninlaro® (ixazomib)
Nubeqa® (darolutamide)
Odomzo® (sonidegib)
Piqray® (alpelisib)
Pomalyst® (pomalidomide)
Revlimid® (lenalidomide)
Rozlytrek™ (entrectinib)
Rubraca® (rucaparib)
Rydapt® (midostaurin)
Sprycel® (dasatinib)
Stivarga® (regorafenib)
Sutent® (sunitinib)
Sylatron™ (peginterferon alfa-2b)
Tagrisso® (osimertinib)
Tafinlar® (dabrafenib)
Talzenna™ (talazoparib)
[a]Tarceva® (erlotinib)
[a]Targretin® (bexarotene)
Tasigna® (nilotinib)
[a]Temodar® (temozolomide)
Thalomid® (thalidomide)
Tibsovo® (ivosidenib)
Tretinoin (oral)
Turalio™ (pexidartinib)
Tykerb® (lapatinib)
Venclexta® (venetoclax)
Verzenio® (abemaciclib)
Vitrakvi® (larotrectinib)
Vizimpro® (dacomitinib)
Votrient® (pazopanib)
Xalkori® (crizotinib)
[a]Xeloda® (capecitabine)
Xospata® (gilteritinib)
Xpovio™ (selinexor)
Xtandi® (enzalutamide)
Yonsa® (abiraterone acetate)
Zejula® (niraparib)
Zelboraf® (vemurafenib)
Zolinza® (vorinostat)
Zydelig® (idelalisib)
Zykadia® (ceritinib)
[a]Zytiga® (abiraterone)
a-generic available

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

QUANTITY LIMIT TARGET AGENTS - RECOMMENDED LIMITS±

Brand (generic)	GPI	Multisource Code	Quantity Per Day Limit
Afinitor (everolimus)			
2.5 mg tablet	21532530000310	M, N, O, or Y	1 tablet
5 mg tablet	21532530000320	M, N, O, or Y	1 tablet
7.5 mg tablet	21532530000325	M, N, O, or Y	1 tablet
10 mg tablet	21532530000330	M, N, O, or Y	1 tablet
Afinitor DISPERZ (everolimus)			
2 mg tablet for oral suspension	21532530007310	M, N, O, or Y	2 tablets^
3 mg tablet for oral suspension	21532530007320	M, N, O, or Y	3 tablets^
5 mg tablet for oral suspension	21532530007340	M, N, O, or Y	2 tablets^
Alecensa (alectinib)			
150 mg capsule	21534007100120	M, N, O, or Y	8 capsules
Alunbrig (brigatinib)			
30 mg tablet	21534010000330	M, N, O, or Y	6 tablets
90 mg tablet	21534010000350	M, N, O, or Y	1 tablet
180 mg tablet	21534010000365	M, N, O, or Y	1 tablet
Starter PAK	2153401000B720	M, N, O, or Y	1 pak/180 days
Balversa (erdafitinib)			
3 mg tablet	21532225000320	M, N, O, or Y	3 tablets
4 mg tablet	21532225000325	M, N, O, or Y	2 tablets
5 mg tablet	21532225000330	M, N, O, or Y	1 tablet
Bosulif (bosutinib)			
100 mg tablet	21534012000320	M, N, O, or Y	4 tablets
400 mg tablet	21534012000327	M, N, O, or Y	1 tablet
500 mg tablet	21534012000340	M, N, O, or Y	1 tablet
Braftovi (encorafenib)			
50 mg capsule	21532040000120	M, N, O, or Y	6 capsules
75 mg capsule	21532040000130	M, N, O, or Y	6 capsules
Cabometyx (cabozantinib)			
20 mg tablet	21534013100320	M, N, O, or Y	1 tablet
40 mg tablet	21534013100330	M, N, O, or Y	1 tablet
60 mg tablet	21534013100340	M, N, O, or Y	1 tablet
Calquence (acalabrutinib)			
100 mg capsule	21534003000120	M, N, O, or Y	2 capsules
Caprelsa (vandetanib)			
100 mg tablet	21534085000320	M, N, O, or Y	2 tablets
300 mg tablet	21534085000340	M, N, O, or Y	1 tablet
Cometriq (cabozantinib)			
140 mg daily dose carton	21534013106480	M, N, O, or Y	1 carton/28 days
100 mg daily dose carton	21534013106470	M, N, O, or Y	1 carton/28 days
60 mg daily dose carton	21534013106460	M, N, O, or Y	1 carton/28 days
Copiktra (duvelisib)			
15 mg capsule	21538030000120	M, N, O, or Y	56 capsules/28 days
25 mg capsule	21538030000130	M, N, O, or Y	56 capsules/28 days
Cotellic (cobimetinib)			
20 mg tablet	21533530200320	M, N, O, or Y	63 tablets/28 days

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

Daurismo (glasdegib)			
25 mg tablet	21370030300320	M, N, O, or Y	2 tablets
100 mg tablet	21370030300335	M, N, O, or Y	1 tablet
Erivedge (vismodegib)			
150 mg capsule	21370070000120	M, N, O, or Y	1 capsule
Erleada (apalutamide)			
60 mg tablet	21402410000320	M, N, O, or Y	4 tablets
Farydak (panobinostat)			
10 mg capsule	21531550100120	M, N, O, or Y	6 capsules/21 days
15 mg capsule	21531550100130	M, N, O, or Y	6 capsules/21 days
20 mg capsule	21531550100140	M, N, O, or Y	6 capsules/21 days
Gilotrif (afatinib)			
20 mg tablet	21534006100320	M, N, O, or Y	1 tablet
30 mg tablet	21534006100330	M, N, O, or Y	1 tablet
40 mg tablet	21534006100340	M, N, O, or Y	1 tablet
Gleevec (imatinib)[a]			
100 mg tablet	21534035100320	M, N, O, or Y	3 tablets
400 mg tablet	21534035100340	M, N, O, or Y	2 tablets
Hexalen (altretamine)			
50 mg capsule	21100005000110	M, N, O, or Y	No Quantity Limit
Hycamtin (topotecan)			
0.25 mg capsule	21550080100120	M, N, O, or Y	No Quantity Limit
1 mg capsule	21550080100140	M, N, O, or Y	No Quantity Limit
Ibrance (palbociclib)			
75 mg capsule	21531060000120	M, N, O, or Y	21 capsules/28 days
100 mg capsule	21531060000130	M, N, O, or Y	21 capsules/ 28 days
125 mg capsule	21531060000140	M, N, O, or Y	21 capsules/28 days
Iclusig (ponatinib)			
15 mg tablet	21534075100320	M, N, O, or Y	2 tablets
45 mg tablet	21534075100340	M, N, O, or Y	1 tablet
Idhifa (enasidenib)			
50 mg tablet	21535030200320	M, N, O, or Y	1 tablet
100 mg tablet	21535030200340	M, N, O, or Y	1 tablet
Imbruvica (ibrutinib)			
70 mg capsule	21534033000110	M, N, O, or Y	1 capsule
140 mg capsule	21534033000120	M, N, O, or Y	4 capsules
140 mg tablet	21534033000320	M, N, O, or Y	1 tablet
280 mg tablet	21534033000330	M, N, O, or Y	1 tablet
420 mg tablet	21534033000340	M, N, O, or Y	1 tablet
560 mg tablet	21534033000350	M, N, O, or Y	1 tablet
Inlyta (axitinib)			
1 mg tablet	21534008000320	M, N, O, or Y	6 tablets
5 mg tablet	21534008000340	M, N, O, or Y	4 tablets
Inrebic (fedratinib)			
100 mg capsule	21537520200120	M, N, O, or Y	4 capsules
Iressa (gefitinib)			
250 mg tablet	21534030000320	M, N, O, or Y	1 tablet
Jakafi (ruxolitinib)			
5 mg tablet	21537560200310	M, N, O, or Y	2 tablets
10 mg tablet	21537560200320	M, N, O, or Y	2 tablets
15 mg tablet	21537560200325	M, N, O, or Y	2 tablets

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

20 mg tablet	21537560200330	M, N, O, or Y	2 tablets
25 mg tablet	21537560200335	M, N, O, or Y	2 tablets
Kisqali (ribociclib)			
200 mg tablet	21531070500320	M, N, O, or Y	63 tablets/28 days
200 mg daily dose pack (200 mg tablets)	2153107050B720	M, N, O, or Y	21 tablets/28 days
400 mg daily dose pack (200 mg tablets)	2153107050B740	M, N, O, or Y	42 tablets/28 days
600 mg daily dose pack (200 mg tablets)	2153107050B760	M, N, O, or Y	63 tablets/28 days
Kisqali Femara Pack (ribociclib and letrozole co-packaged)			
200 mg ribociclib tablets and 2.5 mg letrozole tablets	2199000260B720	M, N, O, or Y	91 tablets/28 days¥
200 mg daily dose co-pack (200 mg ribociclib tablets and 2.5 mg letrozole tablets)	2199000260B730	M, N, O, or Y	49 tablets/28 days¥
400 mg daily dose co-pack (200 mg ribociclib tablets and 2.5 mg letrozole tablets)	2199000260B740	M, N, O, or Y	70 tablets/28 days¥
600 mg daily dose co-pack (200 mg ribociclib tablets and 2.5 mg letrozole tablets)	2199000260B760	M, N, O, or Y	91 tablets/28 days¥
Lenvima (lenvatinib)			
4 mg capsule therapy pack	2153405420B210	M, N, O, or Y	30 capsules/30 days
8 mg (2 x 4 mg capsules daily) therapy pack	2153405420B215	M, N, O, or Y	60 capsules/30 days
10 mg capsule therapy pack	2153405420B220	M, N, O, or Y	30 capsules/30 days
12 mg (3 x 4 mg capsules daily) therapy pack	2153405420B223	M, N, O, or Y	90 capsules/30 days
14 mg (10 mg and 4 mg capsule daily) therapy pack	2153405420B240	M, N, O, or Y	60 capsules/30 days
18 mg (10 mg and 2 x 4 mg capsules daily) therapy pack	2153405420B244	M, N, O, or Y	90 capsules/30 days
20 mg (2 x 10mg capsules daily) therapy pack	2153405420B230	M, N, O, or Y	60 capsules/30 days
24 mg (2 x 10mg and 1 x 4 mg capsules daily)	2153405420B250	M, N, O, or Y	90 capsules/30 days
Lonsurf (trifluridine/tipiracil)			
15 mg/6.14 mg tablet	21990002750320	M, N, O, or Y	100 tablets/28 days
20 mg/ 8.19 mg tablet	21990002750330	M, N, O, or Y	80 tablets/28 days
Lorbrena (lorlatinib)			
25 mg tablet	21534056000320	M, N, O, or Y	3 tablets
100 mg tablet	21534056000330	M, N, O, or Y	1 tablet
Lynparza (olaparib)			
50 mg capsule	21535560000120	M, N, O, or Y	16 capsules
Lynparza (olaparib)			

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

100 mg tablet	21535560000330	M, N, O, or Y	4 tablets
150 mg tablet	21535560000340	M, N, O, or Y	4 tablets
Lysodren (mitotane)			
500 mg tablet	21402250000320	M, N, O, or Y	No Quantity Limit
Matulane (procarbazine)			
50mg capsule	21700050100105	M, N, O, or Y	No Quantity Limit
Mekinist (trametinib)			
0.5 mg tablet	21533570100310	M, N, O, or Y	3 tablets
2 mg tablet	21533570100330	M, N, O, or Y	1 tablet
Mektovi (binimetinib)			
15 mg tablet	21533520000320	M, N, O, or Y	6 tablets
Nerlynx (neratinib)			
40 mg tablet	21534058100320	M, N, O, or Y	6 tablets
Nexavar (sorafenib)			
200 mg tablet	21533060400320	M, N, O, or Y	4 tablets
Ninlaro (ixazomib)			
2.3 mg capsule	21536045100120	M, N, O, or Y	3 capsules/28 days
3 mg capsule	21536045100130	M, N, O, or Y	3 capsules/28 days
4 mg capsule	21536045100140	M, N, O, or Y	3 capsules/28 days
Nubeqa (darolutamide)			
300 mg tablet	21402425000320	M, N, O, or Y	4 tablets
Odomzo (sonidegib)			
200 mg capsule	21370060200120	M, N, O, or Y	30 capsules/30 days
Piqray (alpelisib)			
200 mg daily dose pack (200 mg tablets)	2153801000B720	M, N, O, or Y	1 pack (28 tablets)/28 days
250 mg daily dose pack (200 mg tablets and 50 mg tablets)	2153801000B725	M, N, O, or Y	1 pack (56 tablets)/28 days
300 mg daily dose pack (150 mg tablets)	2153801000B730	M, N, O, or Y	1 pack (56 tablets)/28 days
Pomalyst (pomalidomide)			
1 mg capsule	21450080000110	M, N, O, or Y	21 capsules/28 days
2 mg capsule	21450080000115	M, N, O, or Y	21 capsules/28 days
3 mg capsule	21450080000120	M, N, O, or Y	21 capsules/28 days
4 mg capsule	21450080000125	M, N, O, or Y	21 capsules/28 days
Revlimid (lenalidomide)			
2.5 mg capsule	99394050000110	M, N, O, or Y	1 capsule
5 mg capsule	99394050000120	M, N, O, or Y	1 capsule
10 mg capsule	99394050000130	M, N, O, or Y	1 capsule
15 mg capsule	99394050000140	M, N, O, or Y	21 capsules/28 days
20 mg capsule	99394050000145	M, N, O, or Y	21 capsules/28 days
25 mg capsule	99394050000150	M, N, O, or Y	21 capsules/28 days
Rozlytrek (entrectinib)			
100 mg capsule	21533820000120	M, N, O, or Y	1 capsule
200 mg capsule	21533820000130	M, N, O, or Y	3 capsules
Rubraca (rucaparib)			

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

200 mg tablet	21535570200320	M, N, O, or Y	4 tablets
250 mg tablet	21535570200325	M, N, O, or Y	4 tablets
300 mg tablet	21535570200330	M, N, O, or Y	4 tablets
Rydapt (midostaurin)			
25 mg capsule	21533030000130	M, N, O, or Y	8 capsules
Sprycel (dasatinib)			
20 mg tablet	21534020000320	M, N, O, or Y	3 tablets
50 mg tablet	21534020000340	M, N, O, or Y	1 tablet
70 mg tablet	21534020000350	M, N, O, or Y	1 tablet
80 mg tablet	21534020000354	M, N, O, or Y	1 tablet
100 mg tablet	21534020000360	M, N, O, or Y	1 tablet
140 mg tablet	21534020000380	M, N, O, or Y	1 tablet
Stivarga (regorafenib)			
40 mg tablet	21533050000320	M, N, O, or Y	84 tablets/28 days
Sutent (sunitinib)			
12.5 mg capsule	21533070300120	M, N, O, or Y	3 capsules
25 mg capsule	21533070300130	M, N, O, or Y	1 capsule
37.5 mg capsule	21533070300135	M, N, O, or Y	1 capsule
50 mg capsule	21533070300140	M, N, O, or Y	1 capsule
Sylatron (peginterferon alfa-2b)			
200 mcg vial	21700075206410 21700075206450	M, N, O, or Y	No Quantity Limit
300 mcg vial	21700075206420 21700075206460	M, N, O, or Y	No Quantity Limit
600 mcg vial	21700075206430	M, N, O, or Y	No Quantity Limit
Tafinlar (dabrafenib)			
50 mg capsule	21532025100120	M, N, O, or Y	4 capsules
75 mg capsule	21532025100130	M, N, O, or Y	4 capsules
Tagrisso (osimertinib)			
40 mg tablet	21534065200320	M, N, O, or Y	1 tablet
80 mg tablet	21534065200330	M, N, O, or Y	1 tablet
Talzenna (talazoparib)			
0.25 mg capsule	21535580400110	M, N, O, or Y	3 capsules
1 mg capsule	21535580400120	M, N, O, or Y	1 capsule
Tarceva (erlotinib)[a]			
25 mg tablet	21534025100320	M, N, O, or Y	2 tablets
100 mg tablet	21534025100330	M, N, O, or Y	1 tablet
150 mg tablet	21534025100360	M, N, O, or Y	1 tablet
Targretin (bexarotene)[a]			
75 mg capsule	21708220000120	M, N, O, or Y	No Quantity Limit
Tasigna (nilotinib)			
50 mg capsule	21534060200110	M, N, O, or Y	4 capsules
150 mg capsule	21534060200115	M, N, O, or Y	4 capsules
200 mg capsule	21534060200125	M, N, O, or Y	4 capsules
Temodar (temozolomide)[a]			
5 mg capsule	21104070000110	M, N, O, or Y	No Quantity Limit
20 mg capsule	21104070000120	M, N, O, or Y	No Quantity Limit
100 mg capsule	21104070000140	M, N, O, or Y	No Quantity Limit
140 mg capsule	21104070000143	M, N, O, or Y	No Quantity Limit
180 mg capsule	21104070000147	M, N, O, or Y	No Quantity Limit
250 mg capsule	21104070000150	M, N, O, or Y	No Quantity Limit
Thalomid (thalidomide)			
50 mg capsule	99392070000120	M, N, O, or Y	1 capsule

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

100 mg capsule	99392070000130	M, N, O, or Y	1 capsule
150 mg capsule	99392070000135	M, N, O, or Y	2 capsules
200 mg capsule	99392070000140	M, N, O, or Y	2 capsules
Tibsovo (ivosidenib)			
250 mg tablet	21534940000320	M, N, O, or Y	2 tablets
Tretinoin			
10 mg capsule	21708080000110	M, N, O, or Y	No Quantity Limit
Turalio (pexidartinib)			
200 mg capsule	21534073010120	M, N, O, or Y	4 capsules
Tykerb (lapatinib)			
250 mg tablet	21534050100320	M, N, O, or Y	6 tablets
Venclexta (venetoclax)			
10 mg tablet	21470080000320	M, N, O, or Y	2 tablets
50 mg tablet	21470080000340	M, N, O, or Y	1 tablet
100 mg tablet	21470080000360	M, N, O, or Y	6 tablets
Starter pack	2147008000B720	M, N, O, or Y	1 pack (42 tablets)/180 days
Verzenio (abemaciclib)			
50 mg tablet	21531010000305	M, N, O, or Y	2 tablets
100 mg tablet	21531010000310	M, N, O, or Y	2 tablets
150 mg tablet	21531010000315	M, N, O, or Y	2 tablets
200 mg tablet	21531010000320	M, N, O, or Y	2 tablets
Vitrakvi (larotrectinib)			
25 mg capsule	21533835200120	M, N, O, or Y	6 capsules
100 mg capsule	21533835200150	M, N, O, or Y	2 capsules
20 mg/mL oral solution	21533835202020	M, N, O, or Y	10 mLs
Vizimpro (dacomitinib)			
15 mg tablet	21534019000320	M, N, O, or Y	1 tablet
30 mg tablet	21534019000330	M, N, O, or Y	1 tablet
45 mg tablet	21534019000340	M, N, O, or Y	1 tablet
Votrient (pazopanib)			
200 mg tablet	21534070100320	M, N, O, or Y	4 tablets
Xalkori (crizotinib)			
200 mg capsule	21534015000120	M, N, O, or Y	2 capsules
250 mg capsule	21534015000125	M, N, O, or Y	2 capsules
Xeloda (capecitabine)[a]			
150 mg tablet	21300005000320	M, N, O, or Y	No Quantity Limit
500 mg tablet	21300005000350	M, N, O, or Y	No Quantity Limit
Xospata (gilteritinib)			
40 mg tablet	21534031200320	M, N, O, or Y	3 tablets
Xpovio (selinexor)			
60 mg once weekly therapy pack (20 mg tablets)	2156006000B750	M, N, O, or Y	12 tablets (1 box)/28 days
80 mg once weekly therapy pack (20 mg tablets)	2156006000B740	M, N, O, or Y	16 tablets (1 box)/28 days
80 mg twice weekly therapy pack (20 mg tablets)	2156006000B720	M, N, O, or Y	32 tablets (1 box)/28 days
100 mg once weekly therapy pack (20 mg tablets)	2156006000B730	M, N, O, or Y	20 tablets (1 box)/28 days
Xtandi (enzalutamide)			

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

40 mg capsule	21402430000120	M, N, O, or Y	4 capsules
Yonsa (abiraterone acetate)			
125 mg tablet	21406010200310	M, N, O, or Y	4 tablets
Zejula (niraparib)			
100 mg capsule	21535550200120	M, N, O, or Y	3 capsules
Zelboraf (vemurafenib)			
240 mg tablet	21532080000320	M, N, O, or Y	8 tablets
Zolinza (vorinostat)			
100 mg capsule	21531575000120	M, N, O, or Y	4 capsules
Zydelig (idelalisib)			
100 mg tablet	21538040000320	M, N, O, or Y	2 tablets
150 mg tablet	21538040000330	M, N, O, or Y	2 tablets
Zykadia (ceritinib)			
150 mg capsule	21534014000130	M, N, O, or Y	3 capsules
150 mg tablet	21534014000330	M, N, O, or Y	3 tablets
Zytiga (abiraterone)			
250 mg tablet[a]	21406010200320	M, N, O, or Y	4 tablets
500 mg tablet	21406010200330	M, N, O, or Y	2 tablets

a-generic available
±Agents with variable dosing based on the patient's weight, body surface area, blood concentration etc are not subject to quantity limit
^Calculation is based on 4.5 mg/m2 with a standard BSA of 2.0 and rounding up to nearest full dose.[1,2]
¥ Quantity limit of 91 tablets per 28 days includes 63 tablets of ribociclib and 28 tablets of letrozole

PRIOR AUTHORIZATION WITH QUANTITY LIMIT CRITERIA FOR APPROVAL
Initial Evaluation
Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. Information has been provided that indicates the patient is currently being treated with the requested agent
      OR
   B. The prescriber states the patient is being treated with the requested agent AND is at risk if therapy is changed
      OR
   C. ALL of the following:
      i. ONE of the following:
         a. The patient has an FDA approved indication for the requested agent **OR**
         b. The patient has an indication that is supported by compendia for the requested agent. (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1,IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)] for the requested agent or the prescriber has submitted additional documentation supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required)

      AND

      ii. ONE of the following:
         a. ALL of the following:
            1. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent

AND

2. Genetic/specific diagnostic testing has been completed

AND

3. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate

OR

b. The requested indication does NOT require genetic/specific diagnostic testing per FDA labeling or supported by compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent

AND

iii. ONE of the following:

a. The requested agent is approved for use as monotherapy in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication

OR

b. The requested agent will be used with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication

AND

iv. ONE of the following:

a. The requested agent is FDA labeled or supported by compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) as a first-line agent for the requested indication

OR

b. The patient has tried and had an inadequate response to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication

OR

c. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication

AND

2. The patient does not have any FDA labeled contraindications to the requested agent

AND

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

3. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in National Comprehensive Cancer Network (NCCN) to the requested agent

AND

4. ONE of the following:
    A. Quantity limit does NOT apply to the requested agent

    OR

    B. The requested quantity (dose) does NOT exceed the program quantity limit

    OR

    C. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit

        AND

        ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication

        AND

        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

    OR

    D. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit

        AND

        ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication

        AND

        iii. The prescriber has submitted information in support of therapy with a higher dose for the requested indication

Length of Approval: Up to 3 months for dose titration requests over the program quantity limit and Vitrakvi
Up to 12 months for all other requests

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process

AND

2. ONE of the following:
    A. The requested agent is Vitrakvi AND the patient has experienced clinical benefit (i.e., partial response, complete response, or stable disease) with the requested agent

    OR

    B. The requested agent is NOT Vitrakvi

AND

3. The patient does not have any FDA labeled contraindications to the requested agent

AND

4. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in National Comprehensive Cancer Network (NCCN) to the requested agent

AND

5. ONE of the following:

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

A. Quantity limit does NOT apply to the requested agent
OR
B. The requested quantity (dose) does NOT exceed the program quantity limit
OR
C. ALL of the following:
    i. The requested quantity (dose) is greater than the program quantity limit
    AND
    ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
    AND
    iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

D. ALL of the following:
    i. The requested quantity (dose) is greater than the program quantity limit
    AND
    ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
    AND
    iii. The prescriber has submitted information in support of therapy with a higher dose for the requested indication

Length of Approval: Up to 12 months

FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved

Step Therapy Supplement Program Summary

This program applies to Medicaid.

Please note, this does not include or apply to quantity limit questions.

STEP THERAPY SUPPLEMENT
OBJECTIVE
The intent of the Step Therapy Supplement is to provide additional questions, to ensure compliance to MN Statute 62Q.184. These questions will apply if the step therapy component within a Prior Authorization or Step Therapy program is not able to be approved.

CONDITIONS FOR APPROVAL
The requested agent will be approved when ONE of the following are met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    a. A statement by the prescriber that the patient is currently taking the requested agent
    AND
    b. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
    AND
    c. The prescriber states that a change in therapy is expected to be ineffective or cause harm

    OR
2. BOTH of the following
    a. The patient's medication history includes the required prerequisite/preferred agent(s) or a drug in the same pharmacological class with the same mechanism of action as indicated by ONE of the following:
        i. Evidence of a paid claim(s) within the past 999 days
        OR
        ii. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days

    AND
    b. ONE of the following:
        i. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event
        OR
        ii. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s)

    OR
3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: As per program specific criteria

© Copyright Prime Therapeutics LLC. 10/2019 All Rights Reserved