



## 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<sup>3-93</sup>

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<sup>3-93</sup>

Agent	Contraindications
Afinitor/Afinitor Disperz (everolimus)	Hypersensitivity to everolimus, to other rapamycin derivatives
Alecensa (alectinib)	None
Alunbrig (brigatinib)	None
Ayvakit (avapritinib)	None
Balversa (erdafitinib)	None
Bosulif (bosutinib)	Hypersensitivity to bosutinib
Braftovi (encorafenib)	None
Brukinsa (zanubrutinib)	None
Cabometyx (cabozantinib)	None
Calquence (acalabrutinib)	None
Caprelsa (vandetanib)	Congenital long QT syndrome
Cometriq (cabozantinib)	None
Copiktra (duvelisib)	<u>None</u>
Cotellic (cobimetinib)	None
Daurismo (glasdegib)	<u>None</u>
Erivedge (vismodegib)	None
Erleada (apalutamide)	<u>Pregnancy</u>
Farydak (panobinostat)	None
Gilotrif (afatinib)	None
Gleevec (imatinib)	None
Hexalen (altretamine)	Hypersensitivity to altretamine, preexisting severe bone marrow depression, severe neurological toxicity
Hycamtin	Severe hypersensitivity to topotecan

<b>Agent</b>	<b>Contraindications</b>
(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
Koselugo (selumetinib)	None
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
Pemazyre (pemigatinib)	None
Piqray (alpelisib)	Severe hypersensitivity to Piqray or to any of its components
Pomalyst (pomalidomide)	Pregnancy
Retevmo (selpercatinib)	None
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
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
Tabrecta (capmatinib)	None
Tafinlar (dabrafenib)	None

<b>Agent</b>	<b>Contraindications</b>
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
Tazverik (tazemetostat)	None
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
Tukysa (tucatinib)	None
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

## REFERENCES

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## Self-Administered Oncology Agents Prior Authorization with Quantity Limit

### TARGET AGENTS

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

**QUANTITY LIMIT TARGET AGENTS - RECOMMENDED LIMITS<sup>±</sup>**

<b>Brand (generic)</b>	<b>GPI</b>	<b>Multisource Code</b>	<b>Quantity Per Day Limit</b>
<b>Afinitor (everolimus)</b>			
2.5 mg tablet <sup>a</sup>	21532530000310	M, N, O, or Y	1 tablet
5 mg tablet <sup>a</sup>	21532530000320	M, N, O, or Y	1 tablet
7.5 mg tablet <sup>a</sup>	21532530000325	M, N, O, or Y	1 tablet
10 mg tablet	21532530000330	M, N, O, or Y	1 tablet
<b>Afinitor DISPERZ (everolimus)</b>			
2 mg tablet for oral suspension	21532530007310	M, N, O, or Y	2 tablets <sup>^</sup>
3 mg tablet for oral suspension	21532530007320	M, N, O, or Y	3 tablets <sup>^</sup>
5 mg tablet for oral suspension	21532530007340	M, N, O, or Y	2 tablets <sup>^</sup>
<b>Alecensa (alectinib)</b>			
150 mg capsule	21534007100120	M, N, O, or Y	8 capsules
<b>Alunbrig (brigatinib)</b>			
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
<b>Ayvakit (avapritinib)</b>			
100 mg tablet	21534009000320	M, N, O, or Y	1 tablet
200 mg tablet	21534009000330	M, N, O, or Y	1 tablet
300 mg tablet	21534009000340	M, N, O, or Y	1 tablet
<b>Balversa (erdafitinib)</b>			
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
<b>Bosulif (bosutinib)</b>			
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
<b>Braftovi (encorafenib)</b>			
50 mg capsule	21532040000120	M, N, O, or Y	6 capsules
75 mg capsule	21532040000130	M, N, O, or Y	6 capsules
<b>Brukinsa (zanubrutinib)</b>			
80 mg capsule	21534095000120	M, N, O, or Y	4 capsules
<b>Cabometyx (cabozantinib)</b>			
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
<b>Calquence (acalabrutinib)</b>			
100 mg capsule	21534003000120	M, N, O, or Y	2 capsules
<b>Caprelsa (vandetanib)</b>			
100 mg tablet	21534085000320	M, N, O, or Y	2 tablets
300 mg tablet	21534085000340	M, N, O, or Y	1 tablet
<b>Cometriq (cabozantinib)</b>			
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
<b>Copiktra (duvelisib)</b>			

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
<b>Cotellic (cobimetinib)</b>			
20 mg tablet	21533530200320	M, N, O, or Y	63 tablets/28 days
<b>Daurismo (glasdegib)</b>			
25 mg tablet	21370030300320	M, N, O, or Y	2 tablets
100 mg tablet	21370030300335	M, N, O, or Y	1 tablet
<b>Erivedge (vismodegib)</b>			
150 mg capsule	21370070000120	M, N, O, or Y	1 capsule
<b>Erleada (apalutamide)</b>			
60 mg tablet	21402410000320	M, N, O, or Y	4 tablets
<b>Farydak (panobinostat)</b>			
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
<b>Gilotrif (afatinib)</b>			
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
<b>Gleevec (imatinib)<sup>a</sup></b>			
100 mg tablet	21534035100320	M, N, O, or Y	3 tablets
400 mg tablet	21534035100340	M, N, O, or Y	2 tablets
<b>Hexalen (altretamine)</b>			
50 mg capsule	21100005000110	M, N, O, or Y	No Quantity Limit
<b>Hycamtin (topotecan)</b>			
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
<b>Ibrance (palbociclib)</b>			
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
75 mg tablet	21531060000320	M, N, O, or Y	21 tablets/28 days
100 mg tablet	21531060000330	M, N, O, or Y	21 tablets/28 days
125 mg tablet	21531060000340	M, N, O, or Y	21 tablets/28 days
<b>Iclusig (ponatinib)</b>			
15 mg tablet	21534075100320	M, N, O, or Y	2 tablets
45 mg tablet	21534075100340	M, N, O, or Y	1 tablet
<b>Idhifa (enasidenib)</b>			
50 mg tablet	21535030200320	M, N, O, or Y	1 tablet
100 mg tablet	21535030200340	M, N, O, or Y	1 tablet
<b>Imbruvica (ibrutinib)</b>			
70 mg capsule	21534033000110	M, N, O, or Y	1 capsule
140 mg capsule	21534033000120	M, N, O, or Y	2 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
<b>Inlyta (axitinib)</b>			
1 mg tablet	21534008000320	M, N, O, or Y	6 tablets
5 mg tablet	21534008000340	M, N, O, or Y	4 tablets
<b>Inrebic (fedratinib)</b>			
100 mg capsule	21537520200120	M, N, O, or Y	4 capsules
<b>Iressa (gefitinib)</b>			
250 mg tablet	21534030000320	M, N, O, or Y	1 tablet



<b>Jakafi (ruxolitinib)</b>			
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
20 mg tablet	21537560200330	M, N, O, or Y	2 tablets
25 mg tablet	21537560200335	M, N, O, or Y	2 tablets
<b>Kisqali (ribociclib)</b>			
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
<b>Kisqali Femara Pack (ribociclib and letrozole co-packaged)</b>			
200 mg ribociclib tablets and 2.5 mg letrozole tablets	2199000260B720	M, N, O, or Y	91 tablets/28 days <sup>‡</sup>
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 <sup>‡</sup>
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 <sup>‡</sup>
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 <sup>‡</sup>
<b>Koselugo (selumetinib)</b>			
10 mg capsule	21533565500110	M, N, O, or Y	8 capsules
25 mg capsule	21533565500125	M, N, O, or Y	4 capsules
<b>Lenvima (lenvatinib)</b>			
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
<b>Lonsurf (trifluridine/tipiracil)</b>			
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

<b>Lorbrena (lorlatinib)</b>			
25 mg tablet	21534056000320	M, N, O, or Y	3 tablets
100 mg tablet	21534056000330	M, N, O, or Y	1 tablet
<b>Lynparza (olaparib)</b>			
50 mg capsule	21535560000120	M, N, O, or Y	16 capsules
<b>Lynparza (olaparib)</b>			
100 mg tablet	21535560000330	M, N, O, or Y	4 tablets
150 mg tablet	21535560000340	M, N, O, or Y	4 tablets
<b>Lysodren (mitotane)</b>			
500 mg tablet	21402250000320	M, N, O, or Y	No Quantity Limit
<b>Matulane (procarbazine)</b>			
50mg capsule	21700050100105	M, N, O, or Y	No Quantity Limit
<b>Mekinist (trametinib)</b>			
0.5 mg tablet	21533570100310	M, N, O, or Y	3 tablets
2 mg tablet	21533570100330	M, N, O, or Y	1 tablet
<b>Mektovi (binimetinib)</b>			
15 mg tablet	21533520000320	M, N, O, or Y	6 tablets
<b>Nerlynx (neratinib)</b>			
40 mg tablet	21534058100320	M, N, O, or Y	6 tablets
<b>Nexavar (sorafenib)</b>			
200 mg tablet	21533060400320	M, N, O, or Y	4 tablets
<b>Ninlaro (ixazomib)</b>			
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
<b>Nubeqa (darolutamide)</b>			
300 mg tablet	21402425000320	M, N, O, or Y	4 tablets
<b>Odomzo (sonidegib)</b>			
200 mg capsule	21370060200120	M, N, O, or Y	30 capsules/30 days
<b>Pemazyre (pemigatinib)</b>			
4.5 mg tablet	21532260000320	M, N, O, or Y	14 tablets/21 days
9 mg tablet	21532260000330	M, N, O, or Y	14 tablets/21 days
13.5 mg tablet	21532260000340	M, N, O, or Y	14 tablets/21 days
<b>Piqray (alpelisib)</b>			
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
<b>Pomalyst (pomalidomide)</b>			
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
<b>Retevmo (selpercatinib)</b>			
40 mg capsule	21534079000120	M, N, O, or Y	6 capsules
80 mg capsule	21534079000140	M, N, O, or Y	4 capsules
<b>Revlimid (lenalidomide)</b>			
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
<b>Rozlytrek (entrectinib)</b>			
100 mg capsule	21533820000120	M, N, O, or Y	1 capsule
200 mg capsule	21533820000130	M, N, O, or Y	3 capsules
<b>Rubraca (rucaparib)</b>			
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
<b>Rydapt (midostaurin)</b>			
25 mg capsule	21533030000130	M, N, O, or Y	8 capsules
<b>Sprycel (dasatinib)</b>			
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
<b>Stivarga (regorafenib)</b>			
40 mg tablet	21533050000320	M, N, O, or Y	84 tablets/28 days
<b>Sutent (sunitinib)</b>			
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
<b>Sylatron (peginterferon alfa-2b)</b>			
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
<b>Tabrecta (capmatinib)</b>			
150 mg tablet	21534016200320	M, N, O, or Y	4 tablets
200 mg tablet	21534016200330	M, N, O, or Y	4 tablets
<b>Tafinlar (dabrafenib)</b>			
50 mg capsule	21532025100120	M, N, O, or Y	4 capsules
75 mg capsule	21532025100130	M, N, O, or Y	4 capsules
<b>Tagrisso (osimertinib)</b>			
40 mg tablet	21534065200320	M, N, O, or Y	1 tablet
80 mg tablet	21534065200330	M, N, O, or Y	1 tablet
<b>Talzenna (talazoparib)</b>			
0.25 mg capsule	21535580400110	M, N, O, or Y	3 capsules
1 mg capsule	21535580400120	M, N, O, or Y	1 capsule
<b>Tarceva (erlotinib)<sup>a</sup></b>			
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
<b>Targretin (bexarotene)<sup>a</sup></b>			
75 mg capsule	21708220000120	M, N, O, or Y	No Quantity Limit
<b>Tasigna (nilotinib)</b>			
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

<b>Tazverik (tazemetostat)</b>			
200 mg tablet	21533675200320	M, N, O, or Y	8 tablets
<b>Temodar (temozolomide)<sup>a</sup></b>			
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
<b>Thalomid (thalidomide)</b>			
50 mg capsule	99392070000120	M, N, O, or Y	1 capsule
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
<b>Tibsovo (ivosidenib)</b>			
250 mg tablet	21534940000320	M, N, O, or Y	2 tablets
<b>Tretinoin</b>			
10 mg capsule	21708080000110	M, N, O, or Y	No Quantity Limit
<b>Tukysa (tucatinib)</b>			
50 mg tablet	21534080000320	M, N, O, or Y	10 tablets
150 mg tablet	21534080000340	M, N, O, or Y	4 tablets
<b>Turalio (pexidartinib)</b>			
200 mg capsule	21534073010120	M, N, O, or Y	4 capsules
<b>Tykerb (lapatinib)</b>			
250 mg tablet	21534050100320	M, N, O, or Y	6 tablets
<b>Venclexta (venetoclax)</b>			
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
<b>Verzenio (abemaciclib)</b>			
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
<b>Vitrakvi (larotrectinib)</b>			
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
<b>Vizimpro (dacomitinib)</b>			
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
<b>Votrient (pazopanib)</b>			
200 mg tablet	21534070100320	M, N, O, or Y	4 tablets
<b>Xalkori (crizotinib)</b>			
200 mg capsule	21534015000120	M, N, O, or Y	2 capsules
250 mg capsule	21534015000125	M, N, O, or Y	2 capsules
<b>Xeloda (capecitabine)<sup>a</sup></b>			
150 mg tablet	21300005000320	M, N, O, or Y	No Quantity Limit
500 mg tablet	21300005000350	M, N, O, or Y	No Quantity Limit
<b>Xospata (gilteritinib)</b>			
40 mg tablet	21534031200320	M, N, O, or Y	3 tablets

<b>Xpovio (selinexor)</b>			
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
<b>Xtandi (enzalutamide)</b>			
40 mg capsule	21402430000120	M, N, O, or Y	4 capsules
<b>Yonsa (abiraterone acetate)</b>			
125 mg tablet	21406010200310	M, N, O, or Y	4 tablets
<b>Zejula (niraparib)</b>			
100 mg capsule	21535550200120	M, N, O, or Y	3 capsules
<b>Zelboraf (vemurafenib)</b>			
240 mg tablet	21532080000320	M, N, O, or Y	8 tablets
<b>Zolinza (vorinostat)</b>			
100 mg capsule	21531575000120	M, N, O, or Y	4 capsules
<b>Zydelig (idelalisib)</b>			
100 mg tablet	21538040000320	M, N, O, or Y	2 tablets
150 mg tablet	21538040000330	M, N, O, or Y	2 tablets
<b>Zykadia (ceritinib)</b>			
150 mg capsule	21534014000130	M, N, O, or Y	3 capsules
150 mg tablet	21534014000330	M, N, O, or Y	3 tablets
<b>Zytiga (abiraterone)</b>			
250 mg tablet <sup>a</sup>	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/m<sup>2</sup> with a standard BSA of 2.0 and rounding up to nearest full dose.<sup>1,2</sup>

¥ 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 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 an 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**

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 provided 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:
  - 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 provided 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>