BlueCross BlueShield of Alabama

Self Administered Oncology Agents Prior Authorization with Quantity Limit Program Summary

This program does not have the preferred product option.

This program applies to Commercial, Blue Partner, NetResults A series, SourceRx, and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Self Administered Oncology Agents Prior Authorization (PA) program is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or clinical guidelines. The criteria considers appropriate indications as those supported in FDA approved labeling, National Comprehensive Cancer Network (NCCN) with level of evidence 1 or 2A recommendation, AHFS, or Drugdex with level of evidence of 1 or IIa.

TARGET DRUGS

Afinitor® (everolimus)
Afinitor® Disperz (everolimus)
Alecensa® (alectinib)
Alunbrig™ (brigatinib)
Bosulif® (bosutinib)
Braftovi™ (encoragenib)
Cabometyx™ (cabozantinib)
Calquence® (acalabrutinib)
Caprelsa® (vandetanib)
Cometriq™ (cabozantinib)
Copiktra™ (duvelisib)
Cotellic™ (cobimetinib)
Erivedge™ (vismodegib)
Erleada™ (apalutamide)
Farydak® (panobinostat)
Gilotrif® (afatinib)
[a]Gleevec® (imatinib)
Hexalen® (altretamine)
Hycamtin® (topotecan)
Ibrance® (palbociclib)
Iclusig™ (ponatinib)
Idhifa® (enasibenib)
Inlyta® (axitinib)
Imbruvica™ (ibrutinib)
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)
Odomzo® (sonidegib)
Pomalyst® (pomalidomide)
Revlimid® (lenalidomide)
Rubraca™ (rucaparib)
Rydapt® (midostaurin)
Sprycel® (dasatinib)
Stivarga® (regorafenib)
Sutent® (sunitinib)
Sylatron® (peginterferon alfa-2b)
Tagrisso™ (osimertinib)
Tafinlar® (dabrafenib)
Talzenna™ (talazoparib)
Tarceva® (erlotinib)
[a]Targretin® (bexarotene)
Tasigna® (nilotinib)
[a]Temodar® (temozolomide)
Thalomid® (thalidomide)
Tibsovo® (ivosidenib)
Tretinoin® (oral)
Tykerb® (lapatinib)
Venclexta™ (venetoclax)
Verzenio™ (abemaciclib)
Vizimpro® (dacomitinib)
Votrient® (pazopanib)
Xalkori® (crizotinib)
[a]Xeloda® (capecitabine)

Xtandi® (enzalutamide)
Yonsa® (abiraterone acetate)
Zejula™ (niraparib)
Zelboraf® (vemurafenib)
Zolinza® (vorinostat)
Zydelig (idelalisib)
Zykadia™ (ceritinib)
Zytiga™ (abiraterone)
a-generic available

QUANTITY LIMIT TARGET DRUGS - RECOMMENDED LIMITS±

Brand (generic)	GPI	Quantity Per Day Limit
Afinitor (everolimus) oral tablet		
2.5 mg tablet	21532530000310	1 tablet
5 mg tablet	21532530000320	1 tablet
7.5 mg tablet	21532530000325	1 tablet
10 mg tablet	21532530000330	1 tablet
Afinitor DISPERZ (everolimus) oral tablet		
2 mg tablet for oral suspension	21532530007310	2 tablets^
3 mg tablet for oral suspension	21532530007320	3 tablets^
5 mg tablet for oral suspension	21532530007340	2 tablets^
Alecensa (alectinib) oral capsule		
150 mg capsule	21534007100120	8 capsules
Alunbrig (brigatinib) tablet		
30 mg tablet	21534010000330	6 tablets
90 mg tablet	21534010000350	1 tablet
180 mg tablet	21534010000365	1 tablet
PAK	2153401000B720	1 pak/180 days
Bosulif (bosutinib) oral tablet		
100 mg tablet	21534012000320	4 tablets
400 mg tablet	21534012000327	1 tablet
500 mg tablet	21534012000340	1 tablet
Braftovi (encorafenib) oral capsules		
50 mg capsules	21532040000120	6 capsules
75 mg capsules	21532040000130	6 capsules
Cabometyx (cabozantinib) oral tablet		
20 mg tablet	21534013100320	1 tablet
40 mg tablet	21534013100330	1 tablet
60 mg tablet	21534013100340	1 tablet
Calquence (acalabrutinib) oral capsules		
100 mg capsule	21534003000120	2 capsules
Caprelsa (vandetanib) oral tablet		
100 mg tablet	21534085000320	2 tablets
300 mg tablet	21534085000340	1 tablet
Cometriq (cabozantinib) oral capsule		
140 mg daily dose carton	21534013106480	1 carton/28 days
100 mg daily dose carton	21534013106470	1 carton/28 days
60 mg daily dose carton	21534013106460	1 carton/28 days
Copiktra (duvelisib) oral capsule		
15 mg capsule	21538030000120	56 capsules/28 days
25 mg capsule	21538030000130	56 capsules/28 days
Cotellic (cobimetinib) oral tablet		
20 mg tablet	21533530200320	63 tablets/28 days
Erivedge (vismodegib) oral capsule		
150 mg capsule	21370070000120	1 capsule
Erleada (apalutamide) oral tablet		
60 mg tablet	21402410000320	4 tablets

Brand (generic)	GPI	Quantity Per Day Limit
Farydak (panobinostat) oral capsule		
10 mg capsule	21531550100120	6 capsules/21 days
15 mg capsule	21531550100130	6 capsules/21 days
20 mg capsule	21531550100140	6 capsules/21 days
Gilotrif (afatinib) oral tablet		
20 mg tablet	21534006100320	1 tablet
30 mg tablet	21534006100330	1 tablet
40 mg tablet	21534006100340	1 tablet
Gleevec (imatinib) oral tablet		
100 mg tablet	21534035100320	3 tablets
400 mg tablet	21534035100340	2 tablets
Hexalen (altretamine) oral capsule		
50 mg capsule	21100005000110	No Quantity Limit
Hycamtin (topotecan) oral capsule		
0.25 mg capsule	21550080100120	No Quantity Limit
1 mg capsule	21550080100140	No Quantity Limit
Ibrance (palbociclib) oral capsule		
75 mg capsule	21531060000120	21 capsules/28 days
100 mg capsule	21531060000130	21 capsules/ 28 days
125 mg capsule	21531060000140	21 capsules/28 days
Iclusig (ponatinib) oral tablet		
15 mg tablet	21534075100320	2 tablets
45 mg tablet	21534075100340	1 tablet
Idhifa® (enasibenib) oral tablet		
50 mg tablet	21535030200320	1 tablet
100 mg tablet	21535030200340	1 tablet
Imbruvica (ibrutinib) oral capsule		
70 mg capsule	21534033000110	1 capsule
140 mg capsule	21534033000120	4 capsules
140 mg tablet	21534033000320	1 tablet
280 mg tablet	21534033000330	1 tablet
420 mg tablet	21534033000340	1 tablet
560 mg tablet	21534033000350	1 tablet
Inlyta (axitinib) oral tablet		
1 mg tablet	21534008000320	6 tablets
5 mg tablet	21534008000340	4 tablets
Iressa (gefitinib) oral tablet		
250 mg tablet	21534030000320	1 tablet
Jakafi (ruxolitinib) oral tablet		
5 mg tablet	21537560200310	2 tablets
10 mg tablet	21537560200320	2 tablets
15 mg tablet	21537560200325	2 tablets
20 mg tablet	21537560200330	2 tablets
25 mg tablet	21537560200335	2 tablets
Kisqali (ribociclib) oral tablet		
200 mg tablet	21531070500320	63 tablets/28 days
Kisqali Femara Pack (ribociclib and letrozole co-packaged)		
200 mg ribociclib tablets and 2.5 mg letrozole tablets	2199000260B720	91 tablets/28 days¥
Lenvima (lenvatinib) oral capsule		
4 mg capsule therapy pack	2153405420B210	30 capsules/30 days

Brand (generic)	GPI	Quantity Per Day Limit
8 mg (2 x 4 mg capsules daily) therapy pack	2153405420B215	60 capsules/30 days
10 mg capsule therapy pack	2153405420B220	30 capsules/30 days
12 mg (3 x 4 mg capsules daily) therapy pack	2153405420B223	90 capsules/30 days
14 mg (10 mg and 4 mg capsule daily) therapy pack	2153405420B240	60 capsules/30 days
18 mg (10 mg and 2 x 4 mg capsules daily) therapy pack	2153405420B244	90 capsules/30 days
20 mg (2 x 10mg capsules daily) therapy pack	2153405420B230	60 capsules/30 days
24 mg (2 x 10mg and 1 x 4 mg capsules daily)	2153405420B250	90 capsules/30 days
Lonsurf (trifluridine/tipiracil) oral tablet		
15 mg/6.14 mg tablet	21990002750320	100 tablets/28 days
20 mg/8.19 mg tablet	21990002750330	80 tablets/28 days
Lorbrena (lorlatinib) oral tablet		
25 mg tablet	21534056000320	3 tablets
100 mg tablet	21534056000330	1 tablet
Lynparza (olaparib) oral capsule		
50 mg capsule	21535560000120	16 capsules
Lynparza (olaparib) oral tablet		
100 mg tablet	21535560000330	4 tablets
150 mg tablet	21535560000340	4 tablets
Lysodren (mitotane) oral tablet		
500 mg tablet	21402250000320	No Quantity Limit
Matulane (procarbazine) oral capsule		
50mg capsule	21700050100105	No Quantity Limit
Mekinist (trametinib) oral tablet		
0.5 mg tablet	21533570100310	3 tablets
2 mg tablet	21533570100330	1 tablet
Mektovi (binimetinib) oral tablet		
15 mg tablet	21533520000320	6 tablets
Nerlynx (neratinib) oral tablet		
40 mg tablet	21534058100320	6 tablets
Nexavar (sorafenib) oral tablet		
200 mg tablet	21533060400320	4 tablets
Ninlaro (ixazomib) oral capsule		
2.3 mg capsule	21536045100120	3 capsules/28 days
3 mg capsule	21536045100130	3 capsules/28 days
4 mg capsule	21536045100140	3 capsules/28 days
Odomzo (sonidegib) oral capsule		
200 mg capsule	21370060200120	30 capsules/30 days
Pomalyst (pomalidomide) oral capsule		
1 mg capsule	21450080000110	21 capsules/28 days
2 mg capsule	21450080000115	21 capsules/28 days
3 mg capsule	21450080000120	21 capsules/28 days
4 mg capsule	21450080000125	21 capsules/28 days
Revlimid (lenalidomide) oral capsule		
2.5 mg capsule	99394050000110	1 capsule
5 mg capsule	99394050000120	1 capsule
10 mg capsule	99394050000130	1 capsule

Brand (generic)	GPI	Quantity Per Day Limit
15 mg capsule	99394050000140	21 capsules/28 days
20 mg capsule	99394050000145	21 capsules/28 days
25 mg capsule	99394050000150	21 capsules/28 days
Rubraca (rucaparib) oral tablet		
200 mg tablet	21535570200320	4 tablets
250 mg tablet	21535570200325	4 tablets
300 mg tablet	21535570200330	4 tablets
Rydapt (midostaurin) oral capsule		
25 mg capsule	21533030000130	8 capsules
Sprycel (dasatinib) oral tablet		
20 mg tablet	21534020000320	3 tablets
50 mg tablet	21534020000340	1 tablet
70 mg tablet	21534020000350	1 tablet
80 mg tablet	21534020000354	1 tablet
100 mg tablet	21534020000360	1 tablet
140 mg tablet	21534020000380	1 tablet
Stivarga (regorafenib) oral tablet		
40 mg tablet	21533050000320	84 tablets/28 days
Sutent (sunitinib) oral capsule		
12.5 mg capsule	21533070300120	3 capsules
25 mg capsule	21533070300130	1 capsule
37.5 mg capsule	21533070300135	1 capsule
50 mg capsule	21533070300140	1 capsule
Sylatron (peginterferon alfa-2b) injection		
200 mcg	21700075206410 21700075206450	No Quantity Limit
300 mcg	21700075206420 21700075206460	No Quantity Limit
600 mcg	21700075206430 21700075206470	No Quantity Limit
Tafinlar (dabrafenib) oral capsule		
50 mg capsule	21532025100120	4 capsules
75 mg capsule	21532025100130	4 capsules
Tagrisso (osimertinib) oral tablet		
40 mg tablet	21534065200320	1 tablet
80 mg tablet	21534065200330	1 tablet
Talzenna (talazoparib) oral capsule		
0.25 mg capsule	21535580400110	3 capsules
1 mg capsule	21535580400120	1 capsule
Tarceva (erlotinib) oral tablet		
25 mg tablet	21534025100320	2 tablets
100 mg tablet	21534025100330	1 tablet
150 mg tablet	21534025100360	1 tablet
Targretin (bexarotene)[a] oral capsule		
75 mg capsule	21708220000120	No Quantity Limit
Tasigna (nilotinib) oral capsule		
50 mg capsule	21534060200110	4 capsules
150 mg capsule	21534060200115	4 capsules
200 mg capsule	21534060200125	4 capsules
Temodar (temozolomide)[a] oral capsule		
5 mg capsule	21104070000110	No Quantity Limit
20 mg capsule	21104070000120	No Quantity Limit

Brand (generic)	GPI	Quantity Per Day Limit
100 mg capsule	21104070000140	No Quantity Limit
140 mg capsule	21104070000143	No Quantity Limit
180 mg capsule	21104070000147	No Quantity Limit
250 mg capsule	21104070000150	No Quantity Limit
Thalomid (thalidomide) oral capsule		
50 mg capsule	99392070000120	1 capsule
100 mg capsule	99392070000130	1 capsule
150 mg capsule	99392070000135	2 capsules
200 mg capsule	99392070000140	2 capsules
Tibsovo (ivosidenib) oral tablet		
250 mg tablet	21534940000320	2 tablets
Tretinoin oral capsule		
10 mg capsule	21708080000110	No Quantity Limit
Tykerb (lapatinib) oral tablet		
250 mg tablet	21534050100320	6 tablets
Venclexta (venetoclax) oral tablet		
10 mg tablet	21470080000320	2 tablets
50 mg tablet	21470080000340	1 tablet
100 mg tablet	21470080000360	4 tablets
Starter pack	2147008000B720	1 pack (42 tablets)/180 days
Verzenio (abemaciclib) oral tablet		
50 mg tablet	21531010000305	2 tablets
100 mg tablet	21531010000310	2 tablets
150 mg tablet	21531010000315	2 tablets
200 mg tablet	21531010000320	2 tablets
Vizimpro (dacomitinib) oral tablet		
15 mg tablet	21534019000320	1 tablet
30 mg tablet	21534019000330	1 tablet
45 mg tablet	21534019000340	1 tablet
Votrient (pazopanib) oral tablet		
200 mg tablet	21534070100320	4 tablets
Xalkori (crizotinib) oral capsule		
200 mg capsules	21534015000120	2 capsules
250 mg capsules	21534015000125	2 capsules
Xeloda (capecitabine)[a] oral tablet		
150 mg tablet	21300005000320	No Quantity Limit
500 mg tablet	21300005000350	No Quantity Limit
Xtandi (enzalutamide) oral capsule		
40 mg capsules	21402430000120	4 capsules
Yonsa (abiraterone acetate) oral tablet		
125 mg tablet	21406010200310	4 tablets
Zejula (niraparib) oral capsule		
100 mg capsules	21535550200120	3 capsules
Zelboraf (vemurafenib) oral tablet		
240 mg tablets	21532080000320	8 tablets
Zolinza (vorinostat) oral capsule		
100 mg capsules	21531575000120	4 capsules
Zydelig (idelalisib) oral tablet		
100 mg tablets	21538040000320	2 tablets
150 mg tablets	21538040000330	2 tablets
Zykadia (ceritinib) oral capsule		
150 mg capsules	21534014000130	5 capsules

Brand (generic)	GPI	Quantity Per Day Limit
Zytiga (abiraterone) oral tablet		
250 mg tablet	21406010200320	4 tablets
500 mg tablet	21406010200330	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.[52, 53]
¥ 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

The target agent will be approved when ALL of the following are met:

1. ONE of the following:
   A. There is documentation that the patient is currently receiving the target agent **OR**
   B. The prescriber states the patient is using the target 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 diagnosis for the target agent **OR**
         b. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™ level of evidence 1 or 2A, AHFS, DrugDex level of evidence 1 or 2A) or the prescriber has submitted additional documentation supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required)

      AND

      ii. Genetic testing has been completed (if applicable) using an FDA approved genetic test if required for therapy with the target agent and results indicate therapy with target agent is appropriate
      AND
      iii. ONE of the following:
         a. The patient has tried and failed the first line agent for the intended indication (if applicable)
            OR
         b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first line agent

   AND
2. The patient does not have an FDA labeled contraindication
   AND
3. The patient does not have an FDA labeled limitation of use that is otherwise not supported in National Comprehensive Cancer Network (NCCN)
   AND
4. ONE of the following:
   A. The quantity is within the program quantity limits
      OR
   B. The quantity (dose) requested is above the program limit, within FDA approved labeling, and the prescribed dose cannot be achieved using a lesser quantity of a higher strength
      OR
   C. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: Up to 3 months for dose titration requests
Up to 12 months for all other requests

FDA Approved Genetic Tests

FDA Companion Diagnostics:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.

FDA APPROVED INDICATIONS[1-51,54-63-73,74-76]

Medication	Indication	Dosing
Afinitor (everolimus)	• Advanced HR+ BC* • RCC* • Renal Angiomyolipoma with TSC • SEGA with TSC • PNET • NET of GI or lung origin[ø]	**Advanced HR+BC, PNET, NET, RCC, renal angiomyolipoma with TSC:** 10 mg once daily **^SEGA and TSC:** 4.5 mg/m^2 once daily, adjusted to attain trough concentrations of 5-15 ng/mL. ^Administration with strong CYP3A4 inducer requires dose of 9 mg/m^2.
Afinitor Disperz (everolimus)	• SEGA with TSC in pediatrics and adults	4.5 mg/m^2 once daily, adjusted to attain trough concentrations of 5-15 ng/mL. Administration with strong CYP3A4 inducer requires dose of 9 mg/m^2.
Alecensa (alectinib)	• ALK positive metastatic NSCLC*	**Metastatic NSCLC:** 600 mg orally twice daily
Alunbrig (brigatinib)	• ALK positive NSCLC*	**NSCLC:** 90 mg orally once daily for the first 7 days; if tolerated, increase to 180 mg orally once daily
Bosulif (bosutinib)	• CML chronic, accelerated or blast phase Ph+*	**CML[±]:** 500 mg orally once daily until disease progression. Consider increasing to 600 mg daily for incomplete response. [±]Adjusted dosing : Renal impairment: 300 mg – 400 mg daily based on CrCl Mild, moderate, severe and hepatic impairment- 200 mg daily
Braftovi (encorafenib)	• In combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	**Melanoma:** 450 mg orally once daily in combination with binimetinib until disease progression or unacceptable toxicity. If adverse reactions are unacceptable, reduce dose to 300 mg once daily. If further dose reduction is required, reduce dose to 200 mg daily. Permanently discontinue if unable to tolerate Braftovi 200 mg once daily.
Cabometyx tablets (cabozantinib)	• RCC	**RCC:** 60 mg orally once daily Do NOT substitute Cabometyx tablets with Cometriq (cabozantinib) capsules
Calquence (acalabrutinib)	• MCL*	**MCL:** 100 mg every 12 hours
Caprelsa (vandetanib)	• Locally advanced or metastatic MTC	**MTC:** 300 mg once daily. Start at 200 mg daily for patients with several renal impairment
Cometriq capsules (cabozantinib)	• MTC	**MTC:** 140 mg orally once daily Do NOT substitute Cometriq (cabozantinib) capsules with Cabometyx (cabozantinib) tablets
Copiktra (duvelisib)	• Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphcytic lymphoma (SLL) after at least two prior therapies	**CLL, SLL, FL**: 25mg orally twice daily. Modify dosage for toxicity.

Medication	Indication	Dosing
	• Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies	
Cotellic (cobimetinib)	• Unresectable or metastatic melanoma with BRAF V600E or V600K mutation[£]	**Melanoma:** 60 mg orally once daily for 21 days of each 28 day cycle
Erivedge (vismodegib)	• BCC	**BCC:** 150 mg orally once daily
Erleada (apalutamide)	• Treatment of patients with non-metastatic castration-resistant prostate cancer	**Non-metastatic castration resistant prostate cancer:** 240 mg once daily Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy
Farydak (panobinostat)	• MM**	**MM:** Treatment phase I: Cycles 1-8, 3 week cycles (total time 24 weeks): • Panobinostat 20 mg orally once every other day for 3 doses per week in weeks 1 and 2 of each 21-day cycle for up to 8 cycles (see label for combination use with bortezomib and dexamethasone) An additional 8 cycles can be considered in those with clinical benefit
Gilotrif (afatinib)	• NSCLC, first line for EGFR substitution mutations[GT] • Progressed metastatic, squamous NSCLC*	**NSCLC:** 40 mg orally once daily
Gleevec[a] (imatinib)	• Ph+ CML • Ph+ CML blast crisis, accelerated phase, chronic phase***** • Ph+ ALL, Ph+ pediatric ALL • MDS/MPD • ASM • HES • CEL • DFSP • GIST	**Ph+ CML:** 400 mg/day in chronic phase; 600 mg/day in accelerated phase or blast crisis; pediatrics 340 mg/m^2/day in chronic phase (not to exceed 600 mg) **ALL:** 600 mg/day; pediatrics 340 mg/m^2/day (not to exceed 600 mg) **MDS/MPD:** 400mg/day **GIST:** 400 mg/day (not to exceed 800 mg/day) **ASM, HES/CEL:** 100-400 mg/day **DFSP:** 800 mg/day
Hexalen (altretamine)	• OC*****	**OC:** 260 mg/m^2/day in 4 divided doses for 14 or 21 consecutive days in a 28 day cycle
Hycamtin (topotecan)	• SCLC*	**SCLC:** 2.3mg/m^2/day for 5 days, repeated every 21 days
Ibrance (palbociclib)	• Advanced/metastatic ER+ HER2 negative BC in: • Postmenopausal women~	**BC:** 125 mg daily for 21 days followed by 7 days off treatment

Medication	Indication	Dosing
	• Women with disease progression following endocrine therapy≠	
Iclusig (ponatinib)	• CML, Ph+ ALL≈ • T315I + CML • T315I +,Ph + ALL	• **CML & Ph+ ALL, T315I + CML, T315I +,Ph + ALL:** 45 mg orally one daily until disease progression.
Idhifa (enasidenib)	• Relapsed or refractory AML with an isocitrate dehydrogenase-2 (IDH2) mutation[GT]	• **AML:** 100 mg orally once daily
Imbruvica (ibrutinib)	• MCL* • CLL/SLL • CLL/SLL with 17p deletion • Waldenströms macroglobulinemia (WM) • Marginal zone lymphoma (MZL)* • Chronic GVHD after failure of one or more lines of systemic therapy	**MCL, MZL**: 560 mg orally once daily. **CLL/SLL, WM, and Chronic GVHD**: 420 mg orally once daily.
Inlyta (axitinib)	• RCC*****	**RCC:** 5 mg orally twice daily. Max dose 10 mg twice daily
Iressa (gefitinib)	• NSCLC, first line for EGFR deletion of exon 19 or exon 21 (L858R) substitution mutations[GT]	**NSCLC:** 250 mg orally once daily
Jakafi (ruxolitinib)	• Myelofibrosis • Polycythemia vera^	**Myelofibrosis:** 5-20 mg orally twice daily depending on platelet count. Max dose is 25 mg twice daily. **Polycythemia vera (PV):** 10 mg orally twice daily
Kisqali (ribociclib)	• HR-positive, HER2 negative advanced or metastatic BC in postmenopausal women	**BC:** 600 mg once daily for 21 days followed by 7 days off.
Kisqali Femara Pack (ribociclib and letrozole co-packaged)	• HR-positive, HER2 negative advanced or metastatic BC in postmenopausal women	**BC:** 600 mg of ribociclib once daily for 21 days followed by 7 days off and 2.5 mg of letrozole once daily continuously for a 28 day cycle.
Lenvima (lenvatinib)	• DTC† • RCC∞	**DTC:** 24 mg orally once daily **RCC:** 18 mg orally once daily (use in combination with everolimus 5mg once daily)
Lonsurf (trifluridine/tipiracil)	• Metastatic CC***	**Metastatic CC:** 35 mg/m2 twice daily on day 1 through 5 and day 8 through 12 of a 28 day cycle. Maximum dose 80 mg twice daily.
Lorbrena (lorlatinib)	• Anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)	**NSCLC:** 100 mg orally once daily

Medication	Indication	Dosing
Lynparza (olaparib) capsules	• BRCA mutated advanced ovarian cancer***GT	**OC:** 400 mg orally twice daily until disease progression or unacceptable toxicity Olaparib capsules are not interchangeable with olaparib tablets on a milligram-to-milligram basis
Lynparza (olaparib) tablets	• Recurrent epithelial OC* • Recurrent FTC* • Recurrent PPC* • BRCA mutated advanced ovarian cancer (OC)***GT • Deleterious or suspected deleterious germline BRCA-mutated, HER-2-negative metastatic BC*GT	**OC, FTC, PPC, BC:** 300 mg orally twice daily Olaparib capsules are not interchangeable with olaparib tablets on a milligram-to-milligram basis
Lysodren (mitotane)	• ACC	**ACC:** 2-6 g/day in 3-4 divided doses titrated up to 9-10 g/day as tolerated. May be titrated higher as tolerated.
Matulane (procarbazine)	• HD	**HD** *MOPP Regimen***:** 100 mg/m^2 daily for 14 days **HD** *single agent adults:* 2-4 mg/kg/day for 1 week, then 4-6mg/kg/day until max response/hematologic toxicity. At max response, maintain 1-2 mg/kg/day. *Pediatric:* 50 mg/m^2/day for 1 week, then 100 mg/m^2/day until max response/hematologic toxicity. At max response, maintain 50 mg/m^2/day (suggested dose- dose should be individualized)
Mekinist (trametinib)	• Metastatic MelanomaGT with BRAF V600E or V600K mutations • Metastatic NSCLC with BRAF V600E mutationGT	**Metastatic melanoma:** 2 mg orally once daily as single agent (BRAF V600E positive) and in combination with dabrafenib (BRAF V600E or V600K positive) **Metastatic NSCLC:** 2 mg orally once daily in combination with dabrafenib
Mektovi (binimetinib)	• In combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	**Melanoma:** 45 mg orally twice daily, approximately 12 hours apart, in combination with encorafenib until disease progression or unacceptable toxicity. If adverse reactions are unacceptable, reduce dose to 30 mg orally twice daily. Permanently discontinue if unable to tolerate Mektovi 30 mg orally twice daily.
Nerlynx (nertinib)	• Early stage HER2-overexpressed/amplified BC after trastuzumab	**BC:** 240 mg orally once daily continuously for one year
Nexavar (sorafenib)	• RCC • HCC	**HCC,RCC,DTC:** 400 mg orally twice daily

Medication	Indication	Dosing
	• DTC	
Ninlaro (ixazomib)	• MM*	**MM:** 4 mg orally on Days 1, 8, and 15 of a 28-day cycle in combination with lenalidomide and dexamethasone
Odomzo (sonidegib)	• Locally advanced BCC	**BCC:** 200 mg orally once daily
Pomalyst (pomalidomide)	• MM**	**MM:** 4 mg once daily on days 1-21 of a repeated 28 day cycle until disease progression. May be used as monotherapy or in combination with dexamethasone.
Revlimid (lenalidomide)	• MM • MM after auto-HSCT • MDS • MCL**	**MM, MCL:** 25 mg once daily on days 1-21 of repeated 28 day cycles (MM-used in combination with dexamethasone) **MM after auto-HSCT:** 10 mg once daily on days 1-28 of repeated 28 day cycles **MDS:** 10 mg once daily
Rubraca (rucaparib)	• OC with deleterious BRCA mutation[GT,**]	**OC:** 600 mg orally twice daily
Rydapt (midostaurin)	• AML with FLT3 mutation[GT, Σ] • ASM • SM-AHN • Mast cell leukemia	**AML:** 50 mg orally twice daily on day 8 to 21 of each cycle **ASM, SM-AHN, Mast cell leukemia:** 100 mg orally twice daily
Sprycel (dasatinib)	• Adults with Ph+ CML, chronic phase • Adults with Ph+ CML, chronic, accelerated, myeloid or lymphoid blast***** • Adults with Ph+ ALL* • Pediatric patients with Ph+ CML, chronic phase	**Adults Ph+ CML:** 100 mg/day in chronic phase **Adults Ph+ ALL, Ph+ CML accelerated, myeloid, or lymphoid blast phase:** 140 mg once daily **Pediatric Chronic phase CML:** 40mg – 140 mg once daily
Stivarga (regorafenib)	• mCRC** • GIST** • HCC*	**GIST, mCRC, or HCC**: 160 mg once daily for the first 21 days of a 28 day cycle.
Sutent (sunitinib)	• Adjuvant RCC • RCC • GIST***** • PNET	**Adjuvant RCC:** 50 mg/day of 4 weeks on treatment followed by 2 weeks off for nine 6-week cycles **GIST or RCC**: 50 mg/day; regimen should be 4 weeks on followed by 2 weeks off **PNET:** 37.5 mg/day continuously, no off period
Sylatron (peginterferon alfa-2b)	• Melanoma	**Melanoma:** 6 mcg/kg/week SC for 8 doses followed by 3 mcg/kg/week SC for up to 5 years
Tafinlar (dabrafenib)	• Metastatic melanoma with BRAF V600E or V600K mutation[GT] • Metastatic NSCLC with BRAF V600E mutation[GT]	**Metastatic melanoma:** 150 mg orally twice daily as a single agent (for BRAF V600E positive) or in combination with trametinib (for BRAF V600E or V600K positive) **Metastatic NSCLC:** 150 mg orally twice daily in combination with trametinib

Medication	Indication	Dosing
Tagrisso (osimertinib)	• Metastatic NSCLC with EGFR T790M mutation*,GT	**Metastatic NSCLC:** 80 mg orally once daily
Talzenna (talazoparib)	• Adult patients with deleterious or suspected deleterious germline BRCA-mutated HER-2 negative locally advanced or metastatic breast cancer	**Metastatic breast cancer:** 1 mg taken as a single oral daily dose
Tarceva (erlotinib)	• NSCLC, first line for EGFR deletion of exon 19 or exon 21 substitutionsGT • NSCLC, maintenance or ≥ 2nd line treatment for EGFR deletion of exon 19 or exon 21 substitution*,GT • PC	**NSCLC:** 150 mg daily **PC**: 100 mg daily
Targretin[a] (bexarotene)	• CTCL*****	**CTCL:** 300 mg/m^2/day
Tasigna (nilotinib)	• Adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase • Adult patients with chronic phase and accelerated phase Ph+ CML resistant to, or intolerant to prior therapy that included imatinib • Pediatric patients greater than or equal to 1 year of age with Ph+ CML chronic phase resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy	**Newly diagnosed Ph+CML**: Adult: 300 mg twice daily Pediatric: 230mg/m^2 twice daily rounded to nearest 50 mg dose **CML *resistant or intolerant to imatinib***: 400 mg twice daily **CML resistant or intolerant to TKI therapy:** 230 mg/m^2 rounded to nearest 50 mg dose
Temodar[a] (temozolomide)	• GBM • AA*****	**GBM:** 75 mg/m^2 for 42 days with focal radiotherapy, then maintenance dose of 150 mg/m^2 once daily for days 1-5 of a 28 day cycle for cycle 1 then dose can be increased to 200 mg/m^2 for days 1-5 of a 28 day cycle based on toxicity, ANC, platelet count for a total of 6 cycles. **AA:** 150 mg/m^2 once daily for 5 consecutive days per 28-day cycle. Dose can be increased to 200 mg/m^2/day for

Medication	Indication	Dosing
		subsequent cycles based on toxicity, ANC, platelet count.
Thalomid (thalidomide)	• MM • ENL, acute treatment and maintenance therapy for prevention and suppression	**MM:** 200 mg once daily in 28 treatment cycles in combination with dexamethasone **ENL**: 100-300mg/day for an episode. Up to 400mg/day for severe cutaneous ENL
Tibsovo (ivosidenib)	• Relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in adults	**AML:** 500 mg orally once daily until disease progression or unacceptable toxicity (a minimum of 6 months)
Tretinoin, oral	• APL*****	**APL:** 45 mg/m^2/day as two divided doses until 30 days after complete remission or 90 days total treatment, whichever occurs first
Tykerb (lapatinib)	• HER2+Metastatic BC****** • HR+HER2+ Metastatic BC	**BC**: 1,250 mg daily on days 1-21 of each cycle **BC HER2+, HR+/HER2+**: 1,500 mg once daily
Venclexta (venetoclax)	• CLL with 17p deletion*,GT	**CLL:** 20 mg once daily (QD) for 7 days on week 1, 50 mg QD for 7 days on week 2, 100 mg QD for 7 days on week 3, 200 mg QD for 7 days on week 4, 400 mg QD on week 5 and thereafter
Verzenio (abemaciclib)	• In combination with fulvestrant for the treatment of women with advanced or metastatic, HR-positive, HER2-negative BC with disease progression following endocrine therapy • As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy • In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with HR-positive, HER2-negative advanced	**In combination with fulvestrant:** 150mg twice daily **Monotherapy**: 200mg twice daily **In combination with an aromatase inhibitor:** 150 mg twice daily

Medication	Indication	Dosing
	or metastatic breast cancer	
Vizimpro (dacomitinib)	• First-line treatment of patients with metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test	**NSCLC:** 45 mg once daily. Reduce dose for adverse reactions.
Votrient (pazopanib)	• RCC • Soft tissue sarcoma*****	**RCC, soft tissue sarcoma:** 800 mg/day
Xalkori (crizotinib)	• Metastatic ALK-positive NSCLC**GT** • Metastatic ROS1-positive NSCLC	**Metastatic NSCLC:** 250 mg orally twice daily.
Xeloda[a] (capecitabine)	• Metastatic BC***** • CC, adjuvant and metastatic	**BC, CC:** 1250 mg/m^2 twice daily for two weeks, then one week rest period, in 3-week cycles
Xtandi (enzalutamide)	• CRPC	**CRPC:** 160 mg orally once daily
Yonsa (abiraterone acetate)	• Metastatic castrate resistant prostate cancer (CRPC)	**CRPC:** 500 mg orally once daily in combination with dexamethasone
Zejula (niraparib)	• Recurrent epithelial OC***** • Recurrent FTC***** • Recurrent PPC*****	**OC, FTC, PPC:** 300 mg once daily
Zelboraf (vemurafenib)	• Metastatic melanoma**GT** • ECD with BRAF V600 mutation	**Metastatic melanoma, ECD:** 960 mg orally twice daily
Zolinza (vorinostat)	• CTCL******	**CTCL:** 400 mg once daily
Zydelig (idelalisib)**Ω**	• Relapsed CLL in combination with rituximab • Relapsed FL****** • Relapsed SLL******	**CLL, FL, SLL:** 150 mg orally twice daily
Zykadia (ceritinib)	• Metastatic ALK-positive NSCLC **GT**	**NSCLC:** 750 mg once daily
Zytiga (abiraterone)	• CRPC • Metastatic high-risk castration-sensitive prostate cancer (CSPC)	**CRPC:** 1000 mg once daily (in combination with prednisone 5 mg twice daily). Reduce dose to 250 mg once daily in patients with baseline moderate hepatic impairment **CSPC:** 1000 mg orally once daily (in combination with prednisone 5mg once daily)

AA-anaplastic astrocytoma, ACC-adrenal cortical carcinoma, ALL-acute lymphoblastic leukemia, AML- acute myeloid leukemia, APL-acute promyelocytic, auto-HSCT- autologous hematopoietic stem cell transplantation, leukemia, ASM-aggressive systemic mastocytosis, BC-breast cancer, BCC – basal cell carcinoma, CC – colorectal cancer, CEL-chronic eosinophilic leukemia, CLL-chronic lymphocytic leukemia, CML-chronic myelogenous leukemia, CRPC-castration-resistant prostate cancer, CTCL- cutaneous T-cell lymphoma, DTC- differentiated thyroid carcinoma, DFSP-dermatofibrosarcoma protuberans, ECD – erdheim-chester disease, ENL- Erythema nodosum leprosum, FL-B-cell non-Hodgkin lymphoma, FTC- fallopian tube cancer, HER2- human epidermal growth factor receptor 2, HES-

Medication	Indication	Dosing
hyperosinophilic syndrome, HR+- hormone receptor positive, GBM- glioblastoma multiforme, GIST-gastrointestinal stromal tumor, GVHD –graft versus host disease, HCC-hepatocellular carcinoma, HL-Hodgkin's Disease, , MDS – myelodysplastic syndrome, MDS/MPD-myelodysplastic/myeloproliferative disease, MM-multiple myeloma, MTC-medullary thyroid cancer, NET- neuroendocrine tumor, NSCLC-non small cell lung cancer, OC-ovarian cancer, PC-pancreatic cancer, PNET-pancreatic neuroendocrine tumors, PPC- primary peritoneal cancer, RCC-renal cell carcinoma, HR+BC-hormone receptor positive breast cancer, SCLC-small cell lung cancer, SEGA- subependymal giant cell astrocytoma, SLL- small lymphocytic lymphoma, SM-AHN- systemic mastocytosis with associated hematological neoplasm, TSC-tuberous sclerosis complex, mCRC – metastatic colorectal cancer, MCL – mantle cell lymphoma		

* Following one previous therapy based on FDA label
**Following two previous therapies based on FDA label
***Following three previous therapies based on FDA label
[GT] Genetic test with a companion diagnostic device required based on FDA label
[a] – generic available
^- for patient who have had an inadequate response to or are intolerant to hydroxyurea
~ Must be taken in combination with letrozole 2.5 mg once daily given continuously throughout the 28-day cycle
† for patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory DTC
£ Use in combination with Zelboraf (vemurafenib)
≠ To be used in combination with fulvestrant: recommended dose is 500 mg administered on Days 1, 15, 29, and once monthly thereafter
Ø Includes progressive, well-differentiated, non-functional tumors that are unresectable, locally advanced or metastatic
∞ to be used with 5 mg everolimus
Ω Zydelig is not indicated and is not recommended for first-line treatment of any patient
[≈] Use in patients for whom no other tyrosine kinase inhibitor is indicated
[Σ] Use in combination with standard cytarabine plus daunorubicin induction and cytarabine consolidation

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 or 2A recommendation, AHFS, or Drugdex with level of evidence of 1 or IIa.

SAFETY[1-51, 54-63-69]

Agent	Contraindications
Afinitor/Afinitor Disperz (everolimus)	Hypersensitivity to everolimus, to other rapamycin derivatives, or to any of the excipients
Alecensa (alectinib)	None
Alunbrig (brigatinib)	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
Erivedge (vismodegib)	None
Erleada (apalutamide)	Pregnancy
Farydak (panobinostat)	None
Gilotrif (afatinib)	None
Gleevec (imatinib)	None

Agent	Contraindications
Hexalen (altretamine)	Hypersensitivity to altretamine, Bone marrow suppression, severe neurological toxicity
Hycamtin (topotecan)	Bone marrow suppression, hyper-sensitivity to topotecan or its ingredients
Ibrance (palbociclib)	None
Iclusig (ponatinib)	None
Idhifa (enasidenib)	None
Imbruvica (ibrutinib)	None
Inlyta (axitinib)	None
Iressa (gefitinib)	None
Jakafi (ruxolitinib)	None
Kisqali (ribociclib)	None
Kisqali Femara Pack (ribociclib and letrozole co-packaged)	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)	Hypersensitivity to mitotane
Matulane (procarbazine)	Bone marrow suppression, known hypersensitivity to procarbazine
Mekinist (trametinib)	None
Mektovi (binimetinib)	None
Nerlynx (nertinib)	None
Nexavar (sorafenib)	Known hypersensitivity to sorafenib or its components, use in combination with carboplatin and paclitaxel in patients with squamous cell lung cancer
Ninlaro (ixazomib)	None
Odomzo (sonidegib)	None
Pomalyst (pomalidomide)	Pregnancy
Revlimid (lenalidomide)	Pregnancy, hypersensitivity to lenalidomide
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, Blass B and C), hypersensitivity to peginterferon alfa-2a or peginterferon alfa-2b
Tafinlar (dabrafenib)	None
Tagrisso (osimertinib)	None

Agent	Contraindications
Talzenna (talazoparib)	None
Tarceva (erlotinib)	None
Targretin (bexarotene)	Pregnancy; known hypersensitivity to bexarotene or other components of the product
Tasigna (nilotinib)	Hypokalemia, hypomagnesemia, QT prolongation
Temodar (temozolomide)	Hypersensitivity to dacarbazine (DTIC) or Temodar component
Thalomid (thalidomide)	Pregnancy, thalidomide hypersensitivity
Tibsovo (ivosidenib)	None
Tretinoin (oral)	known hypersensitivity to tretinoin, any of its components, or, retinoid hypersensitivity
Tykerb (lapatinib)	Known hypersensitivity to lapatinib or Tykerb components
Venclexta (venetoclax)	Concomitant use with strong inhibitors of CYP3A at dose initiation and during dose ramp-up phase
Verzenio (abemaciclib)	None
Vizimpro (dacomitinib)	None
Votrient (pazopanib)	None
Xalkori (crizotinib)	None
Xeloda (capecitabine)	Severe renal failure, hypersensitivity to capecitabine or 5-fluorouracil
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)	Women who are or may become pregnant

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