



Formulary changes announced

Changes to the Independent Health Drug formularies resulting from the May 2023 Independent Health Pharmacy and Therapeutics Committee are summarized below and are currently in effect unless otherwise noted.

NPG/NPB - Non-Preferred Generic/Brand
 PG/PB - Preferred Generic/Brand
 NF - Non-Formulary
 SP - Specialty Pharmacy
 PA - Prior Authorization
 ST - Step Therapy

QL - quantity Limits
 SC - subcutaneous
 IM - intramuscular
 inj - injection
 tab - tablet
 cap - capsule
 oph- ophthalmic

soln - solution
 susp - suspension
 MDI-metered-dose inhalation aerosol
 ODT - orally-disintegrating tablet
 LA-available only at certain pharmacies
 G- Generic (T2) for Medicare

Changes to Drug Formulary I (DFI), FEHB Formulary, and Pharmacy Benefit Dimensions Formulary		
Medications Added to Formulary 7/1/2023	Medications Non-Formulary 7/1/2023	Changes to Formulary 7/1/2023
Austedo XR (deutetrabenazine extended-release) tab- NPB PA SP Daybue (trofinetide) oral soln- NPB PA SP LA Filspari (sparsentan) tab- NPB PA Joenja (leniolisib tab)- NPB PA SP LA Skyclarys (omaveloxolone) cap- NPB PA SP LA Vowst (fecal microbiota) cap- NPB PA LA	atropine sulfate ophthalmic 0.025% and 0.05% Combogesic (acetaminophen/ibuprofen) tab Liqrev (sildenafil) oral susp Lumryz (sodium oxybate extended-release) oral sups Motpoly XR (lacosamide extended-release) cap Pradaxa (dabigatran) pallet primidone 125 mg tab Rizafilm (rizatriptan) oral film Symbicort (budesonide/formoterol 160/4.8mcg) aerosphere Tezspire (tezepelumab) SC auto injector Zavzpret (zavegepant) nasal spray	cyclosporin 0.05% ophth emulsion to T1 PA except ophthalmology and optometry (6/1/2023) OTC COVID 19 Testing Kits not covered (5/12/2023) Rhophylac (Rh ₀ immune globulin) PA removed

Changes to Drug Formulary II (DFII), Drug Formulary III (DFIII), and Essential Plan Formulary (EPF)		
Medications Added to Formulary 7/1/2023	Medications Non-Formulary 7/1/2023	Changes to Formulary 7/1/2023
Austedo XR (deutetrabenazine extended-release) tab- NPB PA SP Daybue (trofinetide) oral soln- NPB PA SP LA Filspari (sparsentan) tab- NPB PA Joenja (leniolisib) tab- NPB PA SP LA Skyclarys (omaveloxolone) cap- NPB PA SP LA Vowst (fecal microbiota) cap- NPB PA LA	atropine sulfate ophthalmic 0.025% and 0.05% Combogesic (acetaminophen/ibuprofen) tab Liqrev (sildenafil) oral susp Lumryz (sodium oxybate extended-release) oral sups Motpoly XR (lacosamide extended-release) cap Pradaxa (dabigatran) pallet primidone 125 mg tab Rizafilm (rizatriptan) oral film Symbicort (budesonide/formoterol 160/4.8mcg) aerosphere Tezspire (tezepelumab) SC auto injector Zavzpret (zavegepant) nasal spray	cyclosporin 0.05% ophth emulsion to T1 PA except ophthalmology and optometry (6/1/2023) OTC COVID 19 Testing Kits not covered (5/12/2023; Essential 10/1/2023) Rhophylac (Rh ₀ immune globulin) PA removed

Changes to Child Health Plus Formulary		
Medications Added to Formulary 7/1/2023	Medications Non-Formulary 7/1/2023	Changes to Formulary 7/1/2023
None	atropine sulfate ophthalmic 0.025% and 0.05% Combogesic (acetaminophen/ibuprofen) tab Austedo XR (deutetrabenazine extended-release) tab Daybue (trofinetide) oral soln Filspari (sparsentan) tab Motpoly XR (lacosamide extended-release) cap Liqrev (sildenafil) oral susp Lumryz (sodium oxybate extended-release) oral sups Pradaxa (dabigatran) pallet primidone 125 mg tab Rizafilm (rizatriptan) oral film Symbicort (budesonide/formoterol 160/4.8mcg) aerosphere Tezspire (tezepelumab) SC auto injector Zavzpret (zavegepant) nasal spray	Rhophylac (Rh ₀ immune globulin) PA removed

Changes to Medicare Formulary		
Medications Added to Formulary 7/1/2023	Medications Non-Formulary 7/1/2023	Changes to Formulary 4/1/2023
Austedo XR (deutetrabenazine extended-release) tab- NPB PA Filspari (sparsentan) tab- NPB PA Joenja (leniolisib) tab- NPB PA SP LA Skyclarys (omaveloxolone) cap- NPB PA SP LA Vowst (fecal microbiota) cap- NPB PA	atropine sulfate ophthalmic 0.025% and 0.05% Combogesic (acetaminophen/ibuprofen) tab Daybue (trofinetide) oral soln Liqrev (sildenafil) oral susp Lumryz (sodium oxybate extended-release) oral sups Pradaxa (dabigatran) pallet primidone 125 mg tab Rizafilm (rizatriptan) oral film Symbicort (budesonide/formoterol 160/4.8mcg) aerosphere Takhzyro 150 mg/mL prefilled syringe Tezspire (tezepelumab) SC auto injector Zavzpret (zavegepant) nasal spray	None

COVID-19 Emergency Use Authorizations (EUA):

These EUAs are covered as medical drugs under specially created administration codes for Medicaid and Commercial members. Providers buy-and-bill Independent Health directly. These EUAs are covered under Original Medicare (Part A or Part B) for those members.

- On 3/13/23, the EUA for the **Pfizer-BioNTech COVID-19 vaccine** was amended to authorize a single Omicron BA.4- and BA.5-specific booster dose after the completion of a three-dose Pfizer-BioNTech COVID-19 vaccine series in children 6 months of age to 4 years of age.
- On 4/4/23, the FDA granted an EUA to **Gohibic** (vilobelimab) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation or extracorporeal membrane oxygenation.
- On 4/18/23, the EUAs for both the **Pfizer-BioNTech COVID-19 vaccine** and the **Moderna COVID-19 vaccine** were amended to authorize an additional Omicron BA.4- and BA.5-specific booster dose in patients who are either immunocompromised (at least 2 months after the previous dose) or at least 65 years of age (at least 4 months after the previous dose). In addition, the FDA simplified the vaccine schedule for ages 5 years and older to a single bivalent vaccine dose in patients who have only received monovalent vaccine thus far. Additional bivalent doses have not yet been authorized in younger, non-immunocompromised adults. The monovalent vaccines are also no longer authorized for use in the United States.
- On 4/28/23, the EUA for the **bivalent Pfizer-BioNTech COVID-19 vaccine** was amended to authorize a booster dose to be used at least 1 month after the completion of a three-dose Pfizer-BioNTech COVID-19 vaccine series in immunocompromised children 6 months of age to 4 years of age. The FDA also stated additional boosters can be administered at the discretion of the healthcare provider.

Informational:

- On 3/28/23, the accelerated approval of **Keytruda** (pembrolizumab) for the treatment of patients with unresectable or metastatic microsatellite instability-high or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options was changed to a full approval.
- On 3/29/23, the FDA approved a full Rx-to-OTC switch for **Narcan** (naloxone) nasal spray, a reversal agent for opioid overdose. The drug sponsor states the OTC version will debut on shelves over the summer. While the cost is likely to be less than the prescription version (the sponsor states “under \$50” as opposed to the \$125 prescription version), an exact cost has not been revealed. **Independent Health plans that cover some OTC drugs will cover OTC Narcan with the tier to be determined based on pricing.**
- The **New York State Medicare carve-out** took place starting 4/1/23. The state took back pharmacy benefit administration while Independent Health retains medical benefit administration. Child Health Plus remains unchanged; Independent Health retained pharmacy benefit administration.
- On 4/6/23, the sponsors of **Imbruvica** (ibrutinib) announced they will be voluntarily removing the accelerated approvals for both mantle cell lymphoma in patients who have received at least one prior therapy (did not meet overall survival endpoint) and marginal zone lymphoma in patients who require systemic therapy and have received at least one prior anti-CD20-based therapy (did not meet progression-free survival endpoint).
- On 4/13/23, the FDA announced **new requirements for the prescribing information of all opioid pain medicines** including (1) language on immediate-release opioids stating these products should not be used for an extended period unless the pain remains severe enough to require them and alternative treatments are inadequate, (2) language on extended-release/long-acting opioids recommending only to use them for severe and persistent pain requiring an extended treatment period for which other options are inadequate, (3) warnings regarding opioid-induced hyperalgesia (OIH) including symptoms differentiating OIH from tolerance and withdrawal, and (4) elevated importance of warnings concerning life-threatening respiratory depression including risks associated with using opioids with benzodiazepines or other CNS depressants.
- On 4/26/23, the FDA notified the public of a **recall of Akorn products** as a result of the manufacturer’s declaration of bankruptcy in February 2023 and inability to continue to meet guidelines ensuring the quality of existing products on the market. A full list of recalled products is available at: <https://www.fda.gov/media/167552/download>.
- On 4/28/23, the accelerated approval of **Libtayo** (cemiplimab-rwlc) for the treatment of patients with locally advanced or metastatic BCC who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate was changed to a full approval.

Products removed from market:

- On 3/7/23, the manufacturer of **Makena** (hydroxyprogesterone caproate) agreed to pull the drug from the U.S. market. This drug, indicated to reduce the risk of preterm birth in women with a history of spontaneous preterm delivery, had been under scrutiny for years. An expert FDA panel recommended removing it from the market because it lacked evidence showing the drug improved neonatal morbidity or mortality or any other direct clinical outcome. The FDA ordered immediate market withdrawal of the product and all generics on 4/6/23.
- On 6/30/23, Sunovion will be voluntarily removing both **Kynmobi** (apomorphine) and **Lonhala** (glycopyrrolate) from the U.S. market. This was a business decision and not related to product efficacy or safety.

Line extensions:

Adds:

1. **Erleada** new 240 mg tablet – added to each LOB following current coverage
2. **Gralise** new 450 mg, 750 mg, 900 mg tablets – added to each LOB following current coverage
3. **Lumakras** new 320 mg tablet – added to each LOB following current coverage
4. **Orenitram** new starter packs – added to each LOB following current coverage
5. **Rebinyn** new 3,000-unit option – added to each LOB following current coverage (Medical)
6. **Takhzyro** new 150 mg/mL prefilled syringe – added to each LOB following current coverage except Medicare

Drugs with new indications:

Brand name	Generic name	New indication(s)	Coverage changes
Amjevita	adalimumab-atto	hidradenitis suppurativa in adults	Policy changes
Breo	fluticasone/vilanterol	asthma lower age limit now 5 years of age	AL changes PRN
Caldolor	ibuprofen	lower age limit now 3 months of age	n/a
Cyltezo	adalimumab-adbm	hidradenitis suppurativa in adults	Policy changes
Evkeeza	evinacumab-dgnb	HoFH now down to 5 years of age	Policy changes
Farxiga	dapagliflozin	preserved ejection fraction	None
HyQvia	human immune globulin	indication now down to 2 years of age	AL updates in policy
Hyrimoz	adalimumab-adaz	hidradenitis suppurativa in adults	Policy changes
Kalydeco	ivacaftor	lower age limit now 1 month of age	AL changes in policy
Keytruda	pembrolizumab	urothelial Ca ineligible for cisplatin chemo w/Padcev	Policy changes
Lexapro	escitalopram	GAD down to 7 years of age	AL changes PRN
Livmarli	maralixibat	lower age limit now down to 3 months of age	Policy changes
Mekinist	trametinib	w/dabrafenib, low-grade BRAF V600E+ glioma	Policy changes
Opdivo	nivolumab	melanoma w/lymph node involvement	Policy changes
Opdivo	nivolumab	single agent for melanoma down to 12 years of age	AL updates in policy
Opdivo	nivolumab	w/Yervoy, for melanoma down to 12 years of age	AL updates in policy
Padcev	enfortumab vedotin-ejfv	urothelial Ca ineligible for cisplatin chemo w/Keytruda	Policy changes
Polivy	polatuzumab vedotin-piiq	DLBCL or HGBL in combination with R-CHP	Policy changes
Prevnar 20	pneumococcal 20-valent vaccine	lower age limit now down to 6 weeks of age	AL changes
Qulipta	atogepant	chronic migraine	Policy changes
Rexulti	brexipiprazole	agitation assoc. w/dementia due to Alzheimer's disease	Policy updates
Sogroya	somapacitan-beco	growth failure in ped. patients 2.5 years of age and up	Remains NF
Tafinlar	dabrafenib	w/trametinib, low-grade BRAF V600E+ glioma	Policy changes
Tepezza	teprotumumab-trbw	indication expanded to all pts with thyroid eye disease	Policy changes
Trikafta	elexacaftor/tezacaftor/ivacaftor	indication now down to 2 years of age	AL updates in policy
Verzenio	abemaciclib	Ki-67 testing removed from indication	Policy changes
Yervoy	ipilimumab	w/Opdivo, for melanoma down to 12 years of age	AL updates in policy
Yusimry	adalimumab-aqvh	hidradenitis suppurativa in adults	Policy changes

Medical (effective 7/1/2023):

1. **Abilify Asimtufii** (aripiprazole extended-release) IM injection susp: medical PA
2. **Altuviio** (antihepophilic factor Fc-VWF-XTEN fusion protein-ehtl) IV infusion: medical PA
3. **Arexvy** (RSV vaccine) IM injection: pending result of ACIP recommendations
4. **Lamzede** (velmanase alfa-tycv) IV injection: medical PA
5. **Mydcombi** (tropicamide/phenylephrine): medical (pupil dilation for procedure/exams)
6. **Omisirge** (omidubicel-ONLY) IV infusion: medical PA
7. **Prevduo** (neostigmine/glycopyrrolate): medical PA
8. **Qalsody** (toferson) intrathecal injection: Block due to inconclusive benefit
9. **Rezzayo** (rezafungin) IV injection: medical PA
10. **Syfovre** (pegcetacoplan) intravitreal injection: medical PA
11. **Uzedly** (risperidone ER) SC susp: medical PA
12. **Zynyz** (retifanimab-dlwr) IV injection: medical PA

New generics:

Brands now non-formulary unless otherwise indicated. For Medicaid, medical drugs will be covered as Commercial unless otherwise specified below.

Brand name	Generic name	Generic tier placement/utilization management			
		Commercial/FEHB	Exch/Small/EBP	Child Health Plus	Medicare Indiv/PDP
Aubagio	teriflunomide	T1 PA exc. neuro	T1 PA exc. neuro	T1 PA exc. neuro	T2/T1
Firvang	vancomycin oral susp. (authorized)	T3 PA exc ID/onc	T3 PA exc ID/onc	NF	NF/NF
Fleqsuvy	baclofen suspension (authorized)	NF	NF	NF	NF/NF
Iressa	gefitinib	NPG PA	NPG PA	NF	T5 PA/T1 PA
Millipred	prednisolone	T3	T3	NF	NF/NF
Naftin	naftifine gel	NF	NF	NF	NF/NF
Pylera	bismuth/metronidazole/tetracycline	T3	NF	T1 PA	T4/T1
Uceris	budesonide rectal foam	NF	NF	NF	T4/T1