New Drug Update 2022: What's Hot and What's Not

Wendy L. Wright,
DNP, ANP-BC, FNP-BC, FAANP, FAAN, FNAP
Owner & President:
Wright & Associates Family Healthcare, Amherst
Wright & Associates Family Healthcare, Concord
Owner – Partners in Healthcare Education, LLC

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Disclosures

- Speaker Bureau:
  - Sanofi-Pasteur, Merck, Pfizer: Vaccines
  - AbbVie and Biohaven: Migraines
- Consultant:
  - Sanofi-Pasteur, Merck, Pfizer, Moderna, and Seqirus: Vaccines
  - GlaxoSmithKline: OA and Pain
  - Bayer: Chronic Kidney Disease
  - Idorsia: Insomnia

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Objectives

- Upon completion of this learning activity, the participant will be able to:
  - Identify 10-20 new medications
  - Discuss the use, side effects, drug-drug interactions, and benefits of each of the medications
  - Discuss updates related to labeling, indications, risks associated with various medications

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New Drugs

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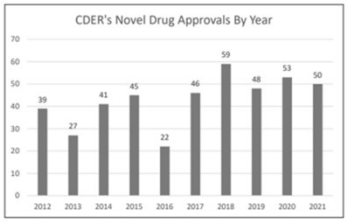
FDA 2022: Center for Drug Evaluation and Research



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Women's Health

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Ibrexafungerp (Brexafemme)

- Name: Ibrexafungerp
- Class:
  - Antifungal indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis
  - Inhibits glucan synthase, an enzyme involved in the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall
  - Has activity against the following species: Candida auris, Candida dubliniensis, Candida glabrata, Candida guilliermondii, Candida keyfr, Candida krusei, Candida lusitaniae, Candida parapsilosis, Candida tropicalis
  - in vitro activity against –azole resistant strains

https://www.brexafemmehcp.com/ accessed 01-15-2022
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Ibrexafungerp

- Dosage:
  - 300 mg twice daily x 1 day (600 mg total)
    - Available in 150 mg tablets
  - Administer 12 hours apart
  - With or without food

https://www.brexafemmehcp.com/ accessed 01-15-2022
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Ibrexafungerp

- Contraindications:
  - Pregnancy (verify pregnancy status is child-bearing age women before administering)
  - Ibrexafungerp administered orally to pregnant rabbits during organogenesis was associated with fetal malformations including absent forelimb(s), absent hindpaw, absent ear pinna, and thoracogastroschisis at dose exposures greater or equal to approximately 5 times the human exposure at the recommended human dose (RHD).
  - Advise women to avoid pregnancy for 4 days after the last dose is taken.

https://www.brexafemmehcp.com/ accessed 01-15-2022
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Ibrexafungerp

- Efficacy
  - 545 women were exposed to drug in two placebo controlled, double blind trials
  - 18 – 76 years of age
- Drug interactions
  - CYP 3A4 substrate
  - Strong 3A4 inhibitors: reduce dose to 150 mg two times daily (12 hours apart)
  - Strong – moderate 3A4 inducers: not studied; avoid

https://www.brexafemmehcp.com/ accessed 01-15-2022
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Ibrexafungerp

- Adverse events (drug vs. placebo)
  - Diarrhea (16.7% vs. 3.3%)
  - Nausea (11.9% vs. 4.0%)
  - Abdominal pain (11.4% vs. 5.1%)
  - Dizziness (3.3% vs. 2.5%)
  - Vomiting (2.0% vs. 0.7%)

https://www.brexafemmehcp.com/ accessed 01-15-2022
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Ibrexafungerp

- Warnings and Precautions
  - No evidence of QT prolongation
- Efficacy (drug vs. placebo)
  - Trial one - complete clinical response
    - 50% vs. 28% (p 0.001)
  - Trial two – complete clinical response
    - 63.5% vs. 44.9% (p 0.009)

https://www.brexafemmehcp.com/ accessed 01-15-2022
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Neurology

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Most controversial approval

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Aducanumab-avwa (Aduhelm)

- Class:
  - An amyloid beta-directed antibody which in clinical trials demonstrated a reduction in amyloid beta plaques
  - Recombinant human immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta
- Indication:
  - Indicated for the treatment of MCI – mild Alzheimer's disease
  - Initiated in the mild dementia stage of Alzheimer's

https://www.biogencdn.com/us/aduhelm-pi.pdf accessed 01-15-2022

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Aducanumab

- Dosing:
  - Titration schedule
  - Dosages must be separated by 21 days
  - IV infusion (every 4 weeks)
    - Infusion 1 and 2: 1 mg/kg over 1 hour
    - Infusion 3 and 4: 3 mg/kg over 1 hour
    - Infusion 5 and 6: 6 mg/kg over 1 hour
    - Infusion 7 and beyond: 10 mg/kg over 1 hour
    - 10 mg/kg: once monthly indefinitely

https://www.biogencdn.com/us/aduhelm-pi.pdf accessed 01-15-2022

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Aducanumab

- Monitoring:
  - MRI within 1 year of starting the medication
  - Obtain repeat MRI after the 6th and before the 7th infusion
  - Obtain repeat prior to the 12th infusion (6th infusion of the maximum dose of 10 mg/kg)
  - There are specific criteria which warrant discontinuation of the infusions (see next slide)

https://www.biogencdn.com/us/aduhelm-pi.pdf accessed 01-15-2022

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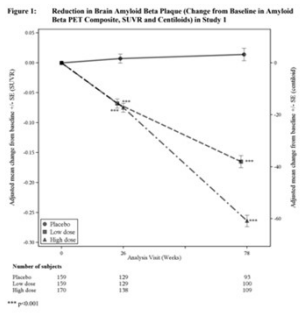
Aducanumab

- https://www.biogencdn.com/us/aduhelm-pi.pdf accessed 01-15-2022



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Aducanumab

- https://www.biogencdn.com/us/aduhelm-pi.pdf accessed 01-15-2022

Table 5: Clinical Results of ADUHELM in Study 1

Clinical Endpoint at Week 78	ADUHELM High dose (N=547)	Placebo (N=548)
CDR-SB		
Mean baseline	2.51	2.47
Change from baseline	1.35	1.74
Difference from placebo (%)	-0.39 (-22%) p=0.0120	
MMSE		
Mean baseline	26.3	26.4
Change from baseline	-2.7	-3.3
Difference from placebo (%)	0.6 (-18%) p=0.0493	
ADAS-Cog 13		
Mean baseline	22.246	21.867
Change from baseline	3.763	5.162
Difference from placebo (%)	-1.400 (-27%) p=0.0097	
ADCS-ADL-MCI		
Mean baseline	42.5	42.6
Change from baseline	-2.5	-4.3
Difference from placebo (%)	1.7 (-40%) p=0.0006	
NPI-10[1]		
Mean baseline	4.5	4.3
Change from baseline	0.2	1.5
Difference from placebo (%)	-1.3 (-87%) p=0.0215	

[1]P-value was not statistically controlled for multiple comparisons.

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Aducanumab

- Adverse events:
  - Amyloid imaging related abnormalities - edema (ARIA-E) which are seen on MRI as brain edema
  - Amyloid imaging related abnormalities – hemosiderin deposition (ARIA-H) which are seen as microhemorrhage and superficial siderosis
  - These were seen in 41% of individuals treated with the 10 mg/kg dosage vs. 10% of placebo

https://www.biogencdn.com/us/aduhelm-pi.pdf accessed 01-15-2022

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Aducanumab

- Adverse events (drug vs. placebo):
  - ARIA-E: 35% vs. 3%
  - Headache: 21% vs. 16%
  - ARIA-H microhemorrhage: 19% vs. 7%
  - ARIA-H superficial siderosis: 15% vs. 2%
  - Fall: (15% vs. 12%)
  - Diarrhea: (9% vs. 7%)
  - Confusion/altered mental status: 8% vs. 4%

https://www.biogencdn.com/us/aduhelm-pi.pdf accessed 01-15-2022

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Aducanumab

- Cost:
  - 100 mg/mL (1 vial, 1.7 mL): $981.00
  - 100 mg/mL (1 vial, 3 mL): $1723.00
  - Estimated to cost about 56,000.00 per year
  - Medicare/CMS expected to make a ruling on covering this medication
  - Biogen planning to cut cost by 50% to spur use

https://www.biogencdn.com/us/aduhelm-pi.pdf accessed 01-15-2022

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Atogepant (Qulipta)

- Class:
  - Calcitonin gene-related peptide receptor antagonist
- Indication:
  - Indicated for the prevention of episodic migraine in adults
- Dosage:
  - 10, 30, or 60 mg taken once daily; with or without food

https://www.rxabbvie.com/pdf/QULIPTA_pi.pdf accessed 01-15-2022

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Atogepant

- Dosing modifications:
  - Strong CYP 3A4 inhibitors: 10 mg once daily
    - Itraconazole, clarithromycin, ketoconazole
  - Strong/Moderate CYP 3A4 inducers:
    - 30 – 60 mg once daily
    - Rifampin, carbamazepine, hypericum
  - OATP inhibitors:
    - 10 or 30 mg once daily
    - Rifampin
  - Severe renal impairment:
    - Creatinine clearance < 30 mL/min: 10 mg once daily

https://www.rxabbvie.com/pdf/QULIPTA_pi.pdf accessed 01-15-2022

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Atogepant

- Efficacy:
  - 1958 patients in clinical trials
  - Two double blind, placebo-controlled trials
  - Trials conducted for 6 and 12 months
  - Allowed to use all "acute treatment medications except other CGRP antagonists)
  - Multiple measures assessed

https://www.rxabbvie.com/pdf/QULIPTA_pi.pdf accessed 01-15-2022

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Atogepant

Monthly Migraine Days 12 weeks	10 mg	30 mg	60 mg	Placebo
Baseline	7.5	7.9	7.8	7.5
Mean change	-3.7	-3.9	-4.2	-2.5
P value	< 0.001	< 0.001	< 0.001	

https://www.rxabbvie.com/pdf/QULIPTA_pi.pdf accessed 01-15-2022

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Atogepant

- Warnings and precautions:
  - Avoid use in pregnancy and lactation
  - Avoid use in severe liver disease
- Adverse events (placebo vs. 10/30/60mg):
  - Nausea (3% vs. 5% vs. 6% vs. 9%)
  - Constipation (1% vs. 6% vs. 6% vs. 6%)
  - Fatigue/somnolence (3% vs. 4% vs. 4% vs. 6%)
  - Decreased appetite (< 1% vs. 2% vs. 1% vs. 2%)
- Contraindications:
  - None
- Cost:
  - 1000.00 for 30 pills

https://www.rxabbvie.com/pdf/QULIPTA_pi.pdf accessed 01-15-2022

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Daridorexant (Quviviq)

- Class:
  - Orexin antagonist
- Indication:
  - Treatment of individuals with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance
- Dosage:
  - 25 mg and 50 mg
  - Likely to be a schedule IV; DEA will rule on schedule in May 2022
  - Coming 2nd quarter 2022

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Cardiology/Nephrology

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Finerenone (Kerendia)

- Class:
  - Non-steroidal mineralocorticoid receptor antagonist (MRA)
  - Finerenone blocks MR mediated sodium reabsorption and MR overactivation in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, and blood vessels) tissues.
  - It has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors
- Indication:

  Reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf accessed 01-18-2022

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Finerenone

- Dosage:
  - 10 mg – 20 mg starting dose based upon eGFR and potassium dosed once daily
    - eGFR: ≥ 60 mL/min: 20 mg once daily
    - eGFR: ≥ 25 to < 60 mL/min: 10 mg once daily
    - eGFR: < 25: not recommended
  - Increase dose to 20 mg once daily at 4 weeks based upon eGFR and serum potassium
  - May be dosed with or without food; may be crushed and mixed with water or soft foods

https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf accessed 01-18-2022

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Finerenone

	10 mg once daily	20 mg once daily
Potassium: ≤ 4.8 mEq/L	Increase dose to 20 mg daily	Maintain dose of 20 mg daily
Potassium: > 4.8 – 5.5 mEq/L	Maintain 10 mg once daily	Maintain dose of 20 mg once daily
Potassium: > 5.5 mEq/L	Withhold finerenone Consider restarting at 10 mg once daily when potassium ≤ 5.0 mEq/L	Withhold finerenone Restart at 10 mg once daily when potassium ≤ 5.0 mEq/L

https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf accessed 01-18-2022

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Finerenone

- Monitoring:
  - Check potassium prior to initiating this medication
  - Do not initiate if potassium is > 5.0 mEq/L
  - Check potassium periodically and prior to increasing dosage

https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf accessed 01-18-2022

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Finerenone

- Efficacy:
  - Reduced the incidence of the primary composite endpoint of a sustained decline in eGFR of ≥ 40%, kidney failure, or renal death.
  - The treatment effect reflected a reduction in a sustained decline in eGFR of ≥40% and reduced progression to kidney failure.
  - Reduced the incidence of the composite endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (MI), non-fatal stroke or hospitalization for heart failure

https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf accessed 01-18-2022

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Finerenone

- Contraindications:
  - Concomitant use of strong CYP 3A4 inhibitors
    - Increased finerenone AUC by > 400%
  - Patients with adrenal insufficiency
- Warnings and precautions:
  - Hyperkalemia; monitor potassium levels and adjust dosage as needed
  - Avoid grapefruit and grapefruit juice
  - Avoid strong or moderate CYP 3A4 inducers
  - Not studied in pregnancy or lactation

https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf accessed 01-18-2022

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Finerenone

- Adverse events (drug vs. placebo):
  - Hyperkalemia (18.3% vs. 9.0%
  - Hypotension (4.8% vs. 3.4%)
  - Hyponatremia (1.4% vs. 0.7%)
- Cost:
  - $600.00 per month

https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf accessed 01-18-2022

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Endocrinology

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Semaglutide (Wegovy)

- Semaglutide (also sold as Ozempic and Rybelsus)
- Class: GLP-1 agonist; injectable
- Indication:
  - BMI 30 or greater or 27.0 or higher with comorbidity
- Dose: 0.25 mg once weekly x 4 weeks; then 0.50 mg once weekly x 4 weeks; 1.0 mg once weekly x 4 weeks; 1.7 mg once weekly x 4 weeks; then a maximum of 2.4 mg once weekly

https://www.novo-pi.com/wegovy.pdf accessed 08-25-2021

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Semaglutide

- Carries same warnings and precautions as GLP-1 agonists
- Okay to use in individuals with CKD
- Efficacy:
  - 3 double-blinded placebo-controlled trials; 2116 patients; Up to 68 weeks
  - Percent of patients losing ≥ 5% of body weight (31.1 vs. 83.5; 30.2 vs. 67.4; 47.8 vs. 84.8)
  - Percent of patients losing ≥ 10 % of body weight (12.0 vs. 66.1; 10.2 vs. 44.5; 27.1 vs. 73.0)
  - Percent of patients losing ≥ 15% of body weight (4.8% vs. 47.9; 4.3 vs. 25.1; 13.2 vs. 53.4)

https://www.novo-pi.com/wegovy.pdf

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Semaglutide

- Side effects:
  - Nausea (44% vs. 16%)
  - Diarrhea (30% vs. 16%)
  - Vomiting (24% vs. 6%)
  - Constipation (24% vs. 11%)
- Cost:
  - Approximately $1350.00 (1 carton, 4 prefilled pens)/month

https://www.novo-pi.com/wegovy.pdf accessed 08-25-2021

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Semaglutide

- Precautions and warnings:
  - Caution with any drug that has a narrow therapeutic index
  - Delays gastric emptying
  - No adjustment for renal or hepatic disease
  - Monitor for depression/suicidality which has been reported in other weight loss trials
  - Monitor heart rate (increase by 1-4 BPM in clinical trials)
  - Supply shortage is limiting access to this medication
    - Main manufacturer has stopped producing product
    - Expect supply chain issues for 1st half of 2022

https://www.novo-pi.com/wegovy.pdf accessed 08-25-2021

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Infectious Disease

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COVID-19 Treatments
EUA Approvals

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Ritonavir-boosted nirmatrelvir (Paxlovid)

EUA approval only

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Ritonavir-boosted nirmatrelvir

- EUA approval: The treatment of mild-to-moderate COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with a positive test for the virus that causes COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

https://www.covid19oralrx-hcp.com/ accessed 01-19-2022

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Ritonavir-boosted nirmatrelvir

- Class:
  - Nirmatrelvir is a SARS-CoV-2 main protease (Mpro) inhibitor
    - Inhibits viral replication
  - Ritonavir is an HIV-1 protease inhibitor
- Study:
  - Phase 2/3, randomized, double-blind, placebo-controlled study in non-hospitalized symptomatic adult subjects with a laboratory confirmed diagnosis of SARS-CoV-2 infection

https://www.covid19oralrx-hcp.com/ accessed 01-19-2022

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Covid-related death or hospitalization within 28 days

- Efficacy:

Placebo (n=1046)	Drug (n=1039)
66	8

https://www.covid19oralrx-hcp.com/ accessed 01-19-2022

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Ritonavir-boosted nirmatrelvir

- Dosing:
  - Initiate as soon as possible after COVID-19 diagnosis and within 5 days of symptom onset
  - Dosed with or without food
  - 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days
  - If the patient misses a dose within 8 hours of the time it is usually taken, the patient should take it as soon as possible and resume the normal dosing schedule

https://www.covid19oralrx-hcp.com/ accessed 01-19-2022

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Ritonavir-boosted nirmatrelvir

- Warnings and precautions:
  - Dose reduction for moderate renal impairment (eGFR ≥30 to 60 mL/min)
    - 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days
  - Not recommended for patients with eGFR < 30 mL/min
  - Not recommended for those with severe liver disease

https://www.covid19oralrx-hcp.com/ accessed 01-19-2022

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Numerous Drug Interactions

- Avoid with the following medications (CY3A cleared):
  - Alpha1-adrenoreceptor antagonist: alfuzosin •Analgesics: pethidine, piroxicam, propoxyphene •Antianginal: ranolazine • Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine • Anti-gout: colchicine • Antipsychotics: lurasidone, pimozide, clozapine • Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine • HMG-CoA reductase inhibitors: lovastatin, simvastatin • PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH) • Sedative/hypnotics: triazolam, oral midazolam

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CYP 3A Inducers

- Will result in decrease in levels and can result in reduced efficacy and drug failure
  - Anticancer drugs: apalutamide
  - Anticonvulsant: carbamazepine, phenobarbital, phenytoin
  - Antimycobacterials: rifampin
  - Herbal products: St. John's Wort (hypericum perforatum)

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Ritonavir-boosted nirmatrelvir

- Adverse events (drug vs. placebo):
  - Dysgeusia (6% vs. <1%)
  - Diarrhea (3% vs. 2%)
  - Hypertension (1% vs. < 1%)
  - Myalgias (1% vs. < 1%)
  - 2% in the treatment group discontinued due to an adverse event; 4% in the placebo arm

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Molnupiravir (MK-4482)

- EUA only; NOT FDA approved
- Indication:
  - Treatment of mild-moderate coronavirus 19 in adults with a positive test and who are at increased risk for progressing to moderate-severe disease
  - Outpatient treatment; not indicated for hospitalized patients
- Class: nucleoside analogue
  - Works by inhibiting viral replication of SARS-CoV 2
  - Results in an accumulation of errors in the viral genome leading to inhibition of replication

https://www.fda.gov/media/155054/download accessed 01-15-2022

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Molnupiravir

- Efficacy:
  - 1433 patients studied in clinical trials
  - Double-blinded, placebo controlled trial
  - Similar efficacy across Alpha, Beta, Gamma, and Delta variants
  - MOVe-OUT Trial

https://www.fda.gov/media/155054/download accessed 01-15-2022

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Molnupiravir

Molnupiravir	Placebo
All-cause hospitalization ≥ 24 hours for acute care or death through day 29 48 (6.8%)	All-cause hospitalization ≥ 24 hours for acute care or death through day 29 68 (9.7%)
All cause mortality through day 29 1 (0.1%)	All cause mortality through day 29 9 (1.3%)

https://www.fda.gov/media/155054/download accessed 01-15-2022

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Molnupiravir

- Dosage:
  - 800 mg every 12 hours x 5 days (available in 200 mg capsules)
  - May be dosed with or without food
  - No dosing adjustments for individuals 65 years of age and older
- Patient instructions:
  - Begin as soon as possible after the onset of symptoms; ideally within 5 days
  - If they miss a dose of molnupiravir and it is within 10 hours of the time it is usually taken, the patient should take it as soon as possible and resume the normal dosing schedule. If > 10 hours, take next dose at regularly scheduled time.

https://www.fda.gov/media/155054/download accessed 01-15-2022

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Molnupiravir

- Contraindications:
  - None at present
  - Not recommended for use in pregnancy or breastfeeding (use contraception for 4 days after the last dose)
    - Oral administration of molnupiravir to pregnant rats during the period of organogenesis resulted in embryofetal lethality and teratogenicity at 8 times the human NHC (N4-hydroxycytidine) exposures at the recommended human dose (RHD)
  - Not approved for children < 18 years
- Adverse reactions (drug vs. placebo):
  - Diarrhea (2% vs. 2%)
  - Dizziness (1% vs. 1%)
  - Nausea (1% vs. 1%)

https://www.fda.gov/media/155054/download accessed 01-15-2022

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Molnupiravir

- Precautions and Warnings
  - Has not been studied in those with eGFR < 30 mL/min
  - Has not been studied in those with moderate-severe liver disease

https://www.fda.gov/media/155054/download accessed 01-15-2022

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Quick Updates and Additional Approvals

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New

- Secnidazole (Solosec)
  - Approved for the treatment of trichomoniasis
  - 2 grams as a single dose
  - ALSO, NEW APPROVAL –
    - 12 years of age and older for BV and trichomoniasis
- Azelastine hydrochloride nasal spray, 0.15% approved for OTC sales; individuals 6 and older

https://www.empr.com/home/news/single-dose-solosec-approved-for-trichomoniasis/?utm_source=newsletter&utm_medium=email&utm_campaign=mpr-dailydose-hay-20210718&cpn=&hmSubId=T456OdVsSjY1&hmEmail=slhn2hv2DuT0GT07edAyLt_fndfC6gdj0&NID=1346274941&c_id=&email_hash=c39006794671 6c8790557377ce89c71c&dl=0&mpweb=1323-142847-1047198 accessed 07-17-2021

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Updates

- Montelukast (Singulair)
  - FDA strengthened warnings re: serious behavior changes and mood changes
- Hydrochlorothiazide
  - Labeling changed to reflect small but increased risk of nonmelanoma skin cancers

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Additional Indications

- Canaglifozin (Invokana): Approved to reduce risk of end-stage renal disease, CV death and risk of hospitalization from CHF
- Dapagliflozin (Farxiga): Approved to reduce the risk of hospitalization from CHF in adults with Type 2 diabetes and cardiovascular disease or multiple cardiovascular risk factors

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Approval

- Fluticasone/umeclidinium/vilanterol (Trelegy Ellipta) approved for asthma maintenance
- Capsaicin 8% patch (Qutenza) - approved for DPN of the feet
- Levonorgestrel-releasing intrauterine system (Mirena) approved for use up to 7 years

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Additional Indications/Approvals or Changes

- Dapagliflozin (Farxiga): approved to reduce hospitalizations in patients with congestive heart failure with reduced EF (HFrEF) – with or without diabetes
- Celecoxib (Elyxyb) – approved for acute migraine
  - 25 mg of celecoxib per every 4.8mL
- Warning of lower extremity amputation removed by the FDA for canagliflozin

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Additional Approval

- Liraglutide (Victoza): approved for Type 2 diabetes in children: ≥ 10 years of age
- Dupilumab (Dupixent): chronic rhinosinusitis in adults with nasal polyposis
  - IL-4 receptor antagonist
  - Already approved for patients with asthma
- Bempedoic acid and ezetimibe (Nexlizet) approved for adjunct to statins for ASCVD or heterozygous familial hypercholesterolemia

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Spinosad (Natroba)

- Topical suspension
- Pediculocide
- Approved for the treatment of scabies in patients 4 years of age and older
- Adverse events:
  - 1% application site irritation and dry skin
- Also indicated for head lice in individuals 6 months of age and older

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Self-injectable Omalizumab (Xolair)

- Moderate-severe asthma, nasal polyposis, or chronic urticaria
- FDA has approved self-injection
- Approved for those with no history of anaphylaxis

FDA approves self-injectable formulation of Xolair (healio.com) accessed 04-27-2021

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Immunizations

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PCV 15 and PCV 20

- Age 65 years:
  - PCV 15 followed by PPSV23 OR
  - PCV 20

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CDC, 2021

Current and Proposed Options for an Age-based Recommendation

	Current Policy	Proposed Policy Option
None of the conditions listed below	PCV13* based on shared clinical decision making, PPSV23 for all	PCV20 **OR** PCV15 and PPSV23
Chronic medical conditions† (CMC)		
Cochlear implant, CSF leak	Both PCV13* and PPSV23	
Immunocompromising conditions		

PCV13: 13-valent pneumococcal conjugate vaccine, PCV15: 15-valent pneumococcal conjugate vaccine, PCV20: 20-valent pneumococcal conjugate vaccine, PPSV23: 23-valent pneumococcal polysaccharide vaccine

*If not previously given; †Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking
https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/02-Pneumococcal-Kobayashi-508.pdf accessed 01-19-2022

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CDC, 2021

Current and Proposed Options for a Risk-Based Recommendation

	Current policy	Proposed Policy Option
None of the conditions listed below	No recommendation	No recommendation
Chronic medical conditions† (CMC)	**PPSV23**	PCV20 **OR** PCV15 and PPSV23
Cochlear implant, CSF leak	**Both PCV13* and PPSV23**	
Immunocompromising conditions	**Both PCV13* and PPSV23, repeat PPSV23 after 5 years**	

PCV13: 13-valent pneumococcal conjugate vaccine
PPSV23: 23-valent pneumococcal polysaccharide vaccine

*If not previously given; †Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking
https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/02-Pneumococcal-Kobayashi-508.pdf accessed 01-19-2022

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Update

- When PCV15 is used, the recommended interval between administration of PCV15 and PPSV23 is ≥1 year
- A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak
- Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23

https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm accessed 02-28-2022

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RZV

- Recombinant Zoster Vaccine (Shingrix)
- Approved by FDA for: 1[illegible] years of age and older; immunocompromised
- Two dose series: day 0 and day 1 month – 2 months
- Now 19 – and up

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Thank you!
I would be happy to entertain any questions or comments

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Wendy L. Wright,
DNP, ANP-BC, FNP-BC, FAANP, FAAN, FNAP
WendyARNP@aol.com

Wright, 2022

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