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RSV Updates: RSV Vaccines and Beyfortus[®] (Nirsevimab)

By Ryan McCormick, PharmD

Vaccine Products

<u>Arexvy[®] (GSK)</u>	<u>Abrysvo[®] (Pfizer)</u>
<ul style="list-style-type: none"> Adjuvanted vaccine Single 0.5 mL IM injection FDA-approved for : <ul style="list-style-type: none"> Prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals age 60+ Does not have maternal vaccine indication Formulary RSV vaccine for Atrium Health Wake Forest Baptist clinics for 60+ indication 	<ul style="list-style-type: none"> Non-adjuvanted, bivalent vaccine Single 0.5 mL IM injection FDA approved for: <ul style="list-style-type: none"> Prevention of lower respiratory tract disease caused by RSV in individuals age 60+ Pregnant individuals 32 - 36 weeks gestation for prevention of RSV LRTD and severe LRTD in infants from birth to 6 months Use restricted to OBGYN clinics for maternal indication and Family Medicine clinics serving <i>both eligible populations</i>

Administration Pearls

- Approaching vaccination for adults age 60+:
 - The CDC recommends using shared clinical decision-making
 - The decision may be informed by a patient's health status, their risk of severe RSV disease, the health care provider's clinical judgement, the patient's preferences, the safety profile of the RSV vaccine products and other factors
 - Risk factors associated with severe disease include:
 - Lung (e.g. COPD, asthma) or cardiovascular diseases (e.g. CHF, CAD)
 - Diabetes mellitus
 - Kidney or liver disorders
 - Hematologic disorders
 - Neurologic or neuromuscular disorders
 - Frailty or advanced age
 - Residence in nursing home or long term care facility
- Dosing Schedule
 - No current recommendations on repeat doses
 - Revaccination after 12 months does not appear to confer additional efficacy benefit, but ongoing clinical trials are evaluating durability of immunity
- Co-administration with other adult vaccines:
 - Clinical trial data support safety of co-administration of influenza and RSV vaccines
 - Co-administration with other adult vaccines is generally acceptable
 - Clinical trials evaluating co-administration with other vaccines are ongoing
- Pregnant patients should be counseled on both options for RSV prevention in infants:
 - Abrysvo[®]
 - Beyfortus[®] (nirsevimab)

RSV Updates: RSV Vaccines and Beyfortus[®] (Nirsevimab), cont.

By Ryan McCormick, PharmD

Beyfortus[®] (nirsevimab)

- Monoclonal antibody targeting RSV F protein
- Single-dose IM injection at beginning of or during RSV season
- Included in Vaccines for Children program
- Recommended for:
 - All infants < 8 months born during or entering their first RSV season:
 - 50 mg if <5 kg
 - 100 mg if ≥5 kg
 - Infants and children 8 - 19 months at increased risk of severe RSV disease entering their second RSV season (same recommendations as Synagis[®] (palivizumab)):
 - 200 mg as two IM doses of 100mg
 - Infants with congenital heart disease should **not** receive if >8 months at start of RSV season

Wake Market Criteria for Use:

OUTPATIENT CRITERIA:

- Infants younger than 8 months, born during or entering their first RSV season
 - Infants born at <34 weeks should receive Beyfortus[®] (nirsevimab) regardless of maternal vaccination status
 - Infants born at ≥34 weeks will **not** need Beyfortus[®] (nirsevimab) if RSV maternal vaccine has been received ≥14 days prior to delivery
- Select populations age 8 - 19 months at increased risk for severe RSV disease entering their second RSV season may receive one dose of Beyfortus[®] (nirsevimab):
 - Children with chronic lung disease of prematurity
 - Children with severe immune compromise
 - Children with cystic fibrosis
 - American Indian or Alaska Native children

INPATIENT CRITERIA (one time dose just prior to discharge):

- Significant prematurity (born <29 weeks, in the first year of life)
- Prematurity with chronic lung disease or bronchopulmonary dysplasia
- Congenital heart disease
- Anatomic pulmonary abnormalities or neuromuscular disease
- Significantly immune compromise
- American Indian or Alaska Native
- Infants <7 days of age at high risk for loss of newborn follow-up care and maternal RSV vaccine has not been received or was received <14 days prior to delivery
- Cystic fibrosis
- Children who have undergone cardiopulmonary bypass or ECMO

Administration Pearls

- Patients with RSV infection in the past 3 months should **not** receive prophylaxis
- No evidence is available to support the use of Beyfortus[®] (nirsevimab) for prevention of hospital-acquired RSV
- Considerations with Synagis[®] (palivizumab):
 - Beyfortus[®] (nirsevimab) appears to have efficacy as high as, or higher than, Synagis[®] (palivizumab), and Beyfortus[®] (nirsevimab) is more cost effective (although no head to head trials exist)
 - Infants who received Beyfortus[®] (nirsevimab), should not receive Synagis[®] (palivizumab) later that season
 - Beyfortus[®] (nirsevimab) should not be administered to those who received Synagis[®] (palivizumab) ≤30 days ago
 - If an infant received Synagis[®] (palivizumab) in season 1 and is eligible for a dose in season 2, Beyfortus[®] (nirsevimab) is preferred for season 2 if available

Gastrointestinal Pathogen (GIP) Panel Updates

By Elizabeth Palavecino, MD

Infectious diarrhea can be caused by bacterial, viral, and parasitic pathogens and remains a significant healthcare burden worldwide. PCR-based multiplex GIP panels have started to replace stool culture and ova and parasite exam as a rapid and accurate means of diagnosing acute gastroenteritis. Infectious diarrhea is usually a self-limited illness and does not need antimicrobial treatment. Many professional organizations, including the Infectious Disease Society of America and the American College of Gastroenterology state that for many gastrointestinal infections, particularly non-inflammatory diarrhea and acute gastroenteritis of short duration, no laboratory testing is recommended. Most payers provide limited coverage for GIP panel testing, particularly in outpatient settings, where testing may be recommended only for specific conditions, such as immunocompromised hosts, the critically ill, or individuals with prolonged disease that is refractory to treatment.

The GIP panel is intended for testing patients with diarrhea that began prior to or less than three days after inpatient admission. **In patients with diarrhea and risks for *C. difficile* infection, the recommendation is to order the stand-alone *C. difficile* Antigen/Toxin EIA.** The GIP panel and the *C. difficile* test should not be ordered at the same time. Careful assessment of the clinical presentation and risk factors are recommended to select the appropriate test. The GIP panel should not be used as a test of cure. Repeat testing on negative results within 7 days during the same episode of diarrhea is not indicated.

Specific recommendations for GIP panel testing:

- Community-acquired acute diarrhea (≥ 3 loose or watery stools/day for ≤ 14 days)

AND AT LEAST ONE of the following:

- >1 week duration AND no laxatives ≤ 48 hours of testing
- Severe illness (e.g., profuse watery diarrhea, signs of hypovolemia, passage of ≥ 6 unformed stools per 24 hours, severe abdominal pain, need for hospitalization)
- Inflammatory diarrhea (e.g. bloody diarrhea, small volume mucus stools, fever, dysentery, dehydration, severe abdominal pain that may warrant hospitalization)
- High-risk host (e.g., age ≥ 70 years, cardiac disease, immunocompromising condition, inflammatory bowel disease, pregnancy)

At Atrium Health Wake Forest Baptist, the microbiology laboratory has offered testing with the GIP panel since January 2015 using BioFire® FilmArray® Gastrointestinal Panel (BioMerieux, Salt Lake City, Utah, USA), which detects the most common bacterial, viral and parasitic (protozoa) organisms that cause diarrhea. A review of internal data shows that the monthly test volume has remained constant despite the addition of specific recommendations for testing in the laboratory test order. For 2022 and 2023 the monthly volume of test orders ranged from 450 to 600 tests, and the monthly positivity rate ranged from 25% to 35% (Figure 1).

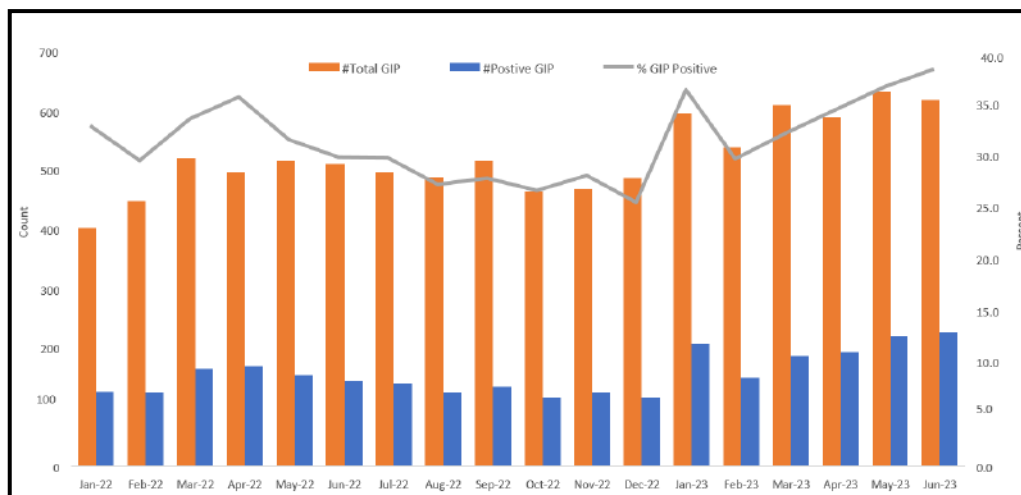


Figure 1. Monthly Volume of GIP Panel Orders at Atrium Health Wake Forest Baptist from January 2022 to June 2023. Includes all GIP panels performed at any Atrium Health Wake Forest market location, including inpatient, ED, and outpatient. The GIP panel is considered positive if at least one pathogen included in the GIP panel is identified by the GIP panel. Figure 1 provided by Tammy Bischoff, Atrium Health Wake Forest Baptist Public Health Epidemiologist.

Gastrointestinal Pathogen (GIP) Panel Updates, cont.

By Elizabeth Palavecino, MD

Approximately 50% of GIP panels are ordered in outpatients, many of whom do not meet the criteria for GIP testing. Overall, the most frequently isolated pathogen is Norovirus followed by *Campylobacter*, Enteropathogenic *E coli* (EPEC), *Salmonella*, and *Shigella* (Figure 2).

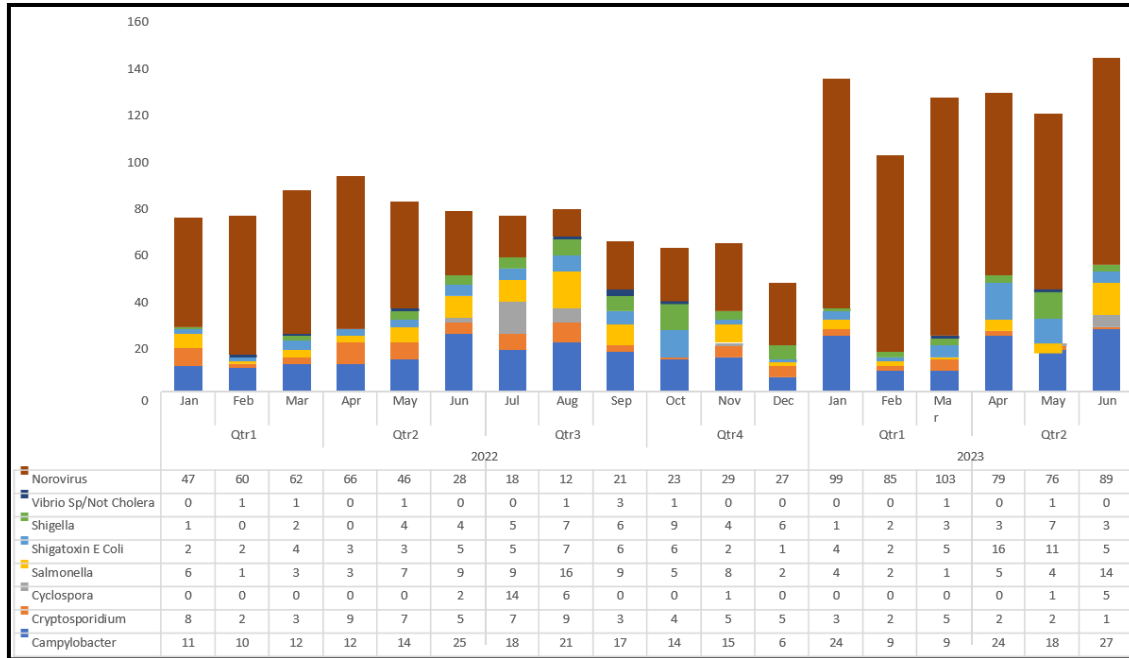


Figure 2: GIP Panel Pathogen Surveillance Data. Includes all GIP panels performed at any Atrium Health Wake Forest market location, including inpatient, ED, and outpatient. Figure 2 provided by Tammy Bischoff, Atrium Health Wake Forest Baptist Public Health Epidemiologist.

Because the GIP panel is a Nucleic Acid Amplification Test (NAAT), detection of an organism does not indicate current infection as the test may remain positive for an extended period of time. Questions on whether treatment is necessary (e.g. positive tests for EPEC) are referred to the antimicrobial stewardship team (CAUSE pager 6494).

New GIP Ordering Process

To improve utilization of the GIP panel, a new GIP panel ordering process was developed across all Advocate Health markets. This process will be available for Atrium Health Wake Forest providers in Encompass in March 2024. Figure 3 illustrates the planned order update, which includes new process instructions and eligibility questions:

Gastrointestinal Pathogen Profile, Stool, NAAT ✔ Accept ✖ Cancel

Add-on: No add-on specimen found

Process Instructions: Acute community acquired gastroenteritis is usually a self-limited illness and therefore testing and treatment may not be necessary. In the case of acute community acquired gastroenteritis, this is not a covered test or routine diarrhea without a prior authorization and may be denied and become the patient responsibility.

Community-acquired acute diarrhea (>= 3 loose or watery stools/day for <=14 days) and at least one of the following indications (check all that apply):

- >1 week duration AND the patient has NOT taken laxatives within 48 hours of the test
- Severe illness (e.g., profuse watery diarrhea, signs of hypovolemia, passage of >=6 unformed stool per 24 hours, severe abdominal pain, need for hospitalization)
- Inflammatory diarrhea (bloody diarrhea, small volume mucus stools, fever, dysentery, dehydration, severe abdominal pain that may warrant hospitalization)
- High-risk host (e.g., >= 70 years, cardiac disease, immunocompromising condition, inflammatory bowel disease (IBD), paralytic ileus, radiation therapy)
- None of the above

⚠ This test is not recommended since no indications were selected. Review indications for utilization of this test and determine whether to proceed with the order.

⚠ By selecting "Yes", I verify that none of the following conditions apply: 1. As a test of cure. 2. Laxatives in the prior to 48 hours, excluding those with signs of severe disease.

The 4-1-1 on Prescribing HIV Pre-Exposure Prophylaxis (PrEP)

By Alex Taylor, PharmD, CPP, BCIDP, AAHIVP

Who can benefit from PrEP?

Recommended for any **HIV-negative** person with:

- Condomless vaginal or anal sex with a partner of unknown HIV status
- HIV-positive sex partner (especially if partner has detectable or unknown viral load)
- Bacterial sexually transmitted infection (STI) ≤ 6 months ago (e.g. gonorrhea, chlamydia, syphilis)
- Survival or transactional sex
- Injection drug use with sharing of needles/equipment
- Desire to conceive with a partner who is HIV-positive
- Requesting PrEP, even if person denies HIV risk factors



Possible HIV exposure in the past 72 hours? →

Offer Non-occupational Post Exposure Prophylaxis (nPEP): **PELine 888-448-4911**

What should I prescribe?

Daily Oral Options:

Emtricitabine/tenofovir disoproxil fumarate (FTC/TDF, Truvada[®], generic equivalent)

- 200 mg/300 mg, 1 tab orally daily, #30, 2 refills for a total supply of no more than 90 days
- Not recommended with CrCl < 60 mL/min

Emtricitabine/tenofovir alafenamide (FTC/TAF, Descovy[®])

- 200 mg/25 mg, 1 tab orally daily, #30, 2 refills for a total supply of no more than 90 days
- Not recommended as PrEP for those at risk from receptive vaginal sex or with CrCl < 30 mL/min

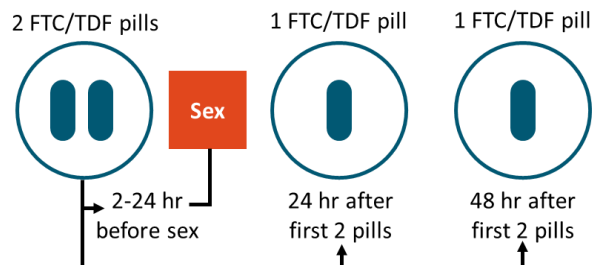
Non-Daily Options:

Cabotegravir (CAB, Apretude[®])

- *Optional:* CAB 30 mg oral daily lead in for one month prior to starting nurse administered injections
- 600 mg, IM injection (gluteal muscle) once a month for 2 months, followed by 600 mg IM injection every 2 months

On-Demand or 2-1-1 Oral PrEP:

- Alternative for men who have sex with men (MSM) *only* who have sex infrequently
- FTC/TDF (Truvada[®], generic equivalent) 200 mg/300 mg, #30, 0 refills (test for HIV before refills)
- Not recommended for other HIV risk groups, with other PrEP regimens, or in hepatitis B (HBV) coinfection
- Dosing:



Side Effects and Precautions

Injectable PrEP (CAB)

- Injection site reactions
- Pregnancy/breastfeeding: discuss benefits/possible risks

Check for drug-drug interactions with any PrEP regimen

Oral PrEP (FTC/TDF, FTC/TAF)

- HBV infection can flare after stopping PrEP medications; check for HBV infection before starting
- Chronic kidney disease; renal dysfunction can occur but is typically reversible after discontinuation (TDF>TAF)
- Osteoporosis; minor loss of bone mineral density over 1 year (1%); no increased fracture risk (TDF>TAF)
- Weight gain (TAF)

The 4-1-1 on Prescribing HIV Pre-Exposure Prophylaxis (PrEP), cont.

By Alex Taylor, PharmD, CPP, BCIDP, AAHIVP

Lab Screening and Visits

	Oral PrEP	Injectable PrEP
Clinical Eligibility	<ul style="list-style-type: none"> Documented negative HIV test result within 1 week of PrEP prescription No signs of acute HIV infection No contraindicated medications or conditions 	
	<ul style="list-style-type: none"> CrCl \geq30mL/min (TAF) or \geq60mL/min (TDF) 	
Baseline Labs	<ul style="list-style-type: none"> HIV Ag/Ab test within 1 week of PrEP initiation <ul style="list-style-type: none"> HIV RNA viral load if possibly infected \leq2 - 4 weeks ago STI testing: gonorrhea/chlamydia (throat, rectum, and genital/urine screen based on anatomical sites of exposure), syphilis, Hepatitis C (HCV) Ab, consider Hepatitis A (HAV) IgG 	
	<ul style="list-style-type: none"> HBV serologies (sAb/cAb/sAg) Serum creatinine Cholesterol and triglycerides (TAF) 	
Follow Up Labs	Every 3 months: <ul style="list-style-type: none"> HIV Ag/Ab test and HIV RNA viral load (in some cases appropriate to assess at 1 month after initiating PrEP in addition to 3 month screening) Bacterial STI screen Pregnancy test if indicated 	1 month after first injection: <ul style="list-style-type: none"> HIV Ag/Ab and HIV RNA viral load
	Every 6 months: <ul style="list-style-type: none"> Assess renal function for persons \geq50 years of age or who have CrCl $<$90mL/min at PrEP initiation 	Every 2 months: <ul style="list-style-type: none"> HIV Ag/Ab and HIV RNA viral load Pregnancy test if indicated
	Every 12 months: <ul style="list-style-type: none"> Assess renal function for all persons Cholesterol and triglycerides (TAF) HCV Ab (MSM, transgender women, persons who inject drugs) Reassess PrEP indication/desire 	Every 4 months: <ul style="list-style-type: none"> Bacterial STI screen Every 12 months: <ul style="list-style-type: none"> Reassess PrEP indication/desire
Follow Up Assessment and Counseling	At every visit: <ul style="list-style-type: none"> Signs and symptoms of acute HIV Adherence to PrEP regimen and risk of stopping PrEP (regimen specific considerations) Adverse effects STI risk and risk reduction behaviors (HIV and bacterial STIs) Contraception/conception planning Access to clean needles/syringes and drug treatment services for persons who inject drugs Importance of regular follow up and laboratory monitoring 	

Key Considerations

- Always refer to CDC PrEP Guidelines for comprehensive recommendations.
- When used as directed, PrEP is highly effective at preventing HIV (> 90%).
- With daily FTC/TDF, maximum blood and rectal tissue drug levels are reached after 7 days and in vaginal tissue after 20 days. For FTC/TAF and CAB, no data on time to protective drug levels are available.
- If planning to stop daily oral PrEP, continue for 28 days after last potential HIV exposure.
- PrEP does not prevent infection with other STIs or pregnancy.

CAUSE Guideline Highlight

Did You Know?

- Institutional [Clostridioides difficile Infection \(CDI\) Adult Diagnosis and Management Guidelines](#) are available on the CAUSE website
- Includes recommendations on:
 - CDI diagnosis and testing
 - Clinical presentation
 - Patient risk factors
 - Treatment principles
 - Antibiotic therapy



P&T Formulary Updates

Drug	Action
Arexvy [®]	<ul style="list-style-type: none"> • RSV vaccine manufactured by GSK • Added to formulary; restricted to outpatient setting for use in adults ≥ 60 years of age
Abrysvo [®]	<ul style="list-style-type: none"> • RSV vaccine manufactured by Pfizer • Added to formulary; restricted to outpatient setting for use in maternal patients only (see exception) & inpatient setting for maternal patients admitted for monitoring until delivery (and will remain admitted during 32–36 weeks' gestation). <i>Exception:</i> For clinic settings that provide care for maternal patients AND adults ≥ 60 years of age, Abrysvo (Pfizer) should be the preferred and only RSV vaccine stocked for both populations.
Beyfortus [®] (Nirsevimab)	<ul style="list-style-type: none"> • RSV monoclonal antibody manufactured by Sanofi Pasteur • Added to formulary; Outpatient and inpatient criteria for use reviewed in detail on page 2
Rebyota [®] (Fecal Microbiota, Live)	<ul style="list-style-type: none"> • Live fecal microbiota product administered rectally for the prevention of recurrence of <i>Clostridioides difficile</i> infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI • Added to formulary; restricted to outpatient use only (endoscopy suite)
Apertude [®] (Cabotegravir)	<ul style="list-style-type: none"> • HIV-1 Integrase Strand Transfer Inhibitor (INSTI) administered intramuscularly every 2 months (after initial injections) for PrEP in adults and adolescents weighing at least 35 kg to reduce the risk of HIV-1 infection • Added to formulary; restricted to outpatient/clinic use only

Meet the CAUSE Staff

The Center for Antimicrobial Utilization, Stewardship, and Epidemiology (CAUSE) is the Antimicrobial Stewardship Program of Atrium Health Wake Forest Baptist (AHWFB). CAUSE was established in 2000 to promote, administrate, and implement antimicrobial stewardship. Daily operation of CAUSE is directed by a core group of clinicians designated as CAUSE staff.

CAUSE activities are consistent with the IDSA/SHEA Antibiotic Stewardship Guidelines. In addition, CAUSE is compliant with TJC standards and the CDC Core Elements of Hospital Antibiotic Stewardship Programs.

It is CAUSE’s philosophy to support and work through the clinicians practicing in various areas throughout the health-system. The program goals are to:

- Prevent or slow the emergence of antimicrobial resistance
- Optimize selection, dose, and duration of antimicrobial treatment
- Reduce adverse drug events
- Reduce morbidity and mortality
- Reduce length of stay
- Reduce health care expenditures



CAUSE Staff Members

Vera Luther, MD, FIDSA CAUSE Medical Director ID Attending Physician	Christopher Ohl, MD, FIDSA CAUSE Assistant Medical Director ID Attending Physician
Alex Taylor, PharmD, CPP, BCIDP, AAHIVP ID Pharmacist	Mary Banoub, PharmD, CPP, BCIDP ID Pharmacist
Olivia Randazza, PharmD, CPP ID Pharmacist	Ryan McCormick, PharmD ID PGY-2 Pharmacy Resident
Charles Hartis, PharmD, BCPS ID Pharmacist	Elizabeth Palavecino, MD Director of Clinical Microbiology Laboratory
Werner Bischoff, MD, PhD, FSHEA Health System Epidemiologist/Director of Infection Prevention and Health System Epidemiology	

The CAUSE Advisory Board (CAB) is a P&T subcommittee that serves to advise, approve, and communicate CAUSE activities and medical staff concerns. It is composed of CAUSE staff, medical staff from selected clinical services, and pharmacy, nursing, and informatics representatives from all Atrium Health Wake Forest market facilities.

CAUSE Resources



Access to:

- Adult and pediatric infectious diseases resources:
 - Treatment guidelines
 - Antimicrobial dosing guidelines
 - Rapid diagnostic guidance
- Antimicrobial stewardship curriculum:
 - Didactic lectures
 - Exam questions
 - Small group activities
- Overview of the institution's antibiotic support team (AST)
- Adult and pediatric prior authorization processes and institutional restricted antimicrobials

Access all current and historical Wake Market Antibiograms on the Atrium Health Wake Forest Baptist Intranet by searching "Antibiograms"

The screenshot shows the Atrium Health Wake Forest Baptist Intranet page. The header includes the Atrium Health logo and the text "Wake Health | School of Medicine". The main navigation bar lists various categories like "About Us", "Human Resources", etc. The breadcrumb trail reads "Home > Departments > Pathology > Resources > Microbiology Susceptibility Studies". The page title is "Antibiograms (Cumulative Susceptibility Reports)". The content is organized by location and year (2022). Under "2022 WF Baptist Medical Center", there are links for "Inpatients", "Inpatients Urine", "Adult ED", "Adult ICU Patients", "Burn Service 2020 - 2022", "Heme-Onc Patients", and "Pediatric Inpatients". Under "Wake Forest Baptist Health Clinics", there are links for "Outpatients", "Outpatient Pediatrics", and "Outpatient Urine". Under "WF Davie Medical Center", there is a link for "Inpatients". Under "WF High Point Medical Center", there is a link for "Inpatients". Under "WF Lexington Medical Center", there is a link for "Inpatients". Under "WF Wilkes Medical Center", there is a link for "Inpatients".