MONOCLONAL ANTIBODIES (mAbs)

Drug Class: Targeted Biologic Immunotherapy

Systems: Immune • Oncology • Rheumatology • Cardiac • Neuro • Respiratory

✦ NCLEX-RN 2026 Test Plan ✦ NGN / NCJMM-Aligned ✦ High-Yield Review ✦

1. DRUG OVERVIEW — WHY WE GIVE IT

KEY INDICATIONS (Target-Specific Biologics):

- **Autoimmune/Inflammatory:** RA, Crohn's, ulcerative colitis, psoriasis, MS, lupus
- **Oncology:** breast CA (HER2+), lymphoma (CD20+), colon CA, leukemia
- **Cardiac/Lipid:** PCSK9 inhibitors for refractory hypercholesterolemia
- **Respiratory:** severe asthma (anti-IgE), RSV prevention in infants
- **Neuro:** migraine prevention (CGRP), Alzheimer's (anti-amyloid)
- **Infectious/Transplant:** COVID-19, prevent organ rejection

HIGH-YIELD CONCEPT:

- **mAbs = "smart bombs"** → lab-made antibodies that bind ONE specific antigen/receptor to block, destroy, or flag cells for the immune system.
- **Suffix clue:** drug name ends in **"-mab"** (monoclonal antibody). Examples: rituxi-**mab**, trastuzu-**mab**, inflixi-**mab**.

2. MECHANISM OF ACTION — SIMPLIFIED

GENERAL PATHWAY:

- Lab-made antibody → binds specific antigen/receptor/cytokine → blocks its function OR flags cell for destruction → ↓ inflammation, ↓ tumor growth, or ↓ immune overactivity

CLASS-SPECIFIC MECHANISMS (HIGH-YIELD):

- **TNF-α inhibitors (infliximab, adalimumab):** block TNF-α → ↓ inflammation in RA/IBD/psoriasis
- **Anti-CD20 (rituximab):** binds CD20 on B-cells → B-cell destruction → ↓ autoimmunity/lymphoma
- **Anti-HER2 (trastuzumab):** blocks HER2 receptor on breast CA cells → ↓ tumor growth
- **Anti-IgE (omalizumab):** binds free IgE → blocks mast cell activation → ↓ asthma attacks
- **Anti-VEGF (bevacizumab):** blocks VEGF → ↓ angiogenesis → ↓ tumor blood supply
- **PCSK9 inhibitors (evolocumab, alirocumab):** block PCSK9 → ↑ LDL receptors → ↓ LDL cholesterol
- **Anti-IL-6 (tocilizumab):** blocks IL-6 → ↓ cytokine storm, ↓ RA inflammation
- **Anti-α4 integrin (natalizumab):** blocks WBC entry into CNS → ↓ MS flares
- **Anti-amyloid (lecanemab, aducanumab):** clear amyloid plaques in Alzheimer's

- **Checkpoint inhibitors (pembrolizumab, nivolumab):** block PD-1 → "release the brakes" on T-cells → attack cancer

3. THERAPEUTIC EFFECTS — IS IT WORKING?

EXPECTED IMPROVEMENTS BY CLASS:

- **Autoimmune (TNF, IL-6):** ↓ joint pain/swelling, ↓ ESR/CRP, ↓ disease flares, improved ADLs
- **Oncology:** tumor shrinkage on imaging, ↓ tumor markers, improved survival
- **Asthma (omalizumab):** ↓ exacerbations, ↓ rescue inhaler use, improved PFTs
- **PCSK9 inhibitors:** LDL drop of 50–60% from baseline
- **MS (natalizumab):** ↓ relapse rate, ↓ new MRI lesions
- **COVID/RSV:** ↓ hospitalization, ↓ severity of illness

REMEMBER:

- **Onset is SLOW** for autoimmune mAbs — full effect may take weeks to months. Educate patient NOT to stop early.

4. SIDE EFFECTS & ADVERSE REACTIONS

COMMON (expected, usually manageable):

- Headache, fatigue, nausea
- Injection site reactions (redness, itching, swelling)
- Mild infusion reactions (flushing, low-grade fever, chills)
- URI symptoms, sinusitis
- Mild rash

SERIOUS / LIFE-THREATENING:

- **INFUSION REACTIONS / ANAPHYLAXIS:** dyspnea, hypotension, wheezing, urticaria, angioedema — MOST COMMON WITH FIRST DOSE
- **SERIOUS INFECTIONS:** reactivation of latent TB, hepatitis B, fungal infections (mAbs are immunosuppressive)
- **TUMOR LYSIS SYNDROME (rituximab):** ↑ K^+, ↑ phosphate, ↑ uric acid, ↓ Ca^{2+} → arrhythmias, AKI
- **CARDIOTOXICITY (trastuzumab):** ↓ ejection fraction, heart failure — especially if combined with doxorubicin
- **PML (natalizumab, rituximab):** progressive multifocal leukoencephalopathy — fatal brain infection caused by JC virus
- **CYTOKINE RELEASE SYNDROME:** fever, hypotension, hypoxia — especially CAR-T and checkpoint inhibitors
- **IMMUNE-RELATED ADVERSE EVENTS (checkpoint inhibitors):** colitis, pneumonitis, hepatitis, thyroiditis, adrenal insufficiency
- **GI PERFORATION / BLEEDING / HTN (bevacizumab):** anti-VEGF impairs wound healing — hold before surgery

- 🚨 **ARIA (anti-amyloid mAbs):** Amyloid-Related Imaging Abnormalities — brain edema/microhemorrhages
- 🚨 **MALIGNANCY RISK:** ↑ risk of lymphoma and skin cancers with long-term TNF inhibitors

🟪 5. PRIORITY NURSING CONSIDERATIONS

BEFORE STARTING (MANDATORY SCREENING):

- → **ASSESS:** TB screen (PPD or IGRA/QuantiFERON) — REQUIRED before TNF inhibitors
- → **ASSESS:** Hepatitis B status (HBsAg, anti-HBc) — risk of reactivation
- → **ASSESS:** Active infection, pregnancy status, immunization status
- → **ASSESS:** Baseline CBC, LFTs, BUN/creatinine, baseline ECHO (if trastuzumab)

DURING / AFTER ADMINISTRATION:

- → **MONITOR:** VS every 15 min during infusion (esp. first dose) — BP, HR, RR, SpO_2, temp
- → **MONITOR:** signs of infusion reaction: dyspnea, flushing, chest tightness, urticaria, hypotension
- → **MONITOR:** infection signs — fever, chills, sore throat, cough, dysuria, wound drainage
- → **MONITOR:** neuro changes (PML: confusion, weakness, vision changes, gait ataxia)

HOLD / NOTIFY HCP IF:

- ⛔ **HOLD:** active infection, fever, suspected TB, live vaccine within 4 weeks
- ⛔ **HOLD:** scheduled surgery (bevacizumab: hold ≥28 days before/after)
- ⛔ **HOLD:** ↓ EF <40% (trastuzumab), severe neutropenia
- ⛔ **HOLD:** signs of PML, severe infusion reaction — STOP infusion immediately

CONTRAINDICATIONS / CAUTIONS:

- Active serious infection (esp. TB, fungal, sepsis)
- Live vaccines (MMR, varicella, yellow fever, nasal flu) — contraindicated during therapy
- Pregnancy (many mAbs Category C/D — cross placenta in T3)
- Heart failure (NYHA III-IV) — avoid TNF inhibitors and trastuzumab
- Demyelinating disease (MS) — avoid TNF inhibitors

KEY DRUG INTERACTIONS:

- Other biologics/immunosuppressants → additive infection risk (never combine 2 biologics)
- Live vaccines → disseminated infection
- Trastuzumab + anthracyclines (doxorubicin) → additive cardiotoxicity
- Natalizumab + immunosuppressants → ↑ PML risk

🟫 6. LABS & DIAGNOSTICS

BASELINE (before first dose):

- TB test: PPD or IGRA — POSITIVE means NO biologic until treated
- Hepatitis B panel (HBsAg, anti-HBc, anti-HBs)
- Hepatitis C screening
- CBC with differential, CMP (LFTs, BUN, creatinine)
- ECHO or MUGA scan (baseline EF) — REQUIRED before trastuzumab
- Pregnancy test in women of childbearing age
- Lipid panel (before PCSK9 inhibitors)

ONGOING MONITORING:

- CBC — watch for neutropenia, thrombocytopenia, anemia
- LFTs — risk of hepatotoxicity/hepatitis reactivation
- BUN/Creatinine — AKI risk, esp. with tumor lysis
- EF q3 months with trastuzumab
- Tumor markers (CA 15-3, CEA) — oncology mAbs
- LDL-C (PCSK9 inhibitors) — target ≥50% reduction
- MRI q6 months (natalizumab) — surveillance for PML

⚠ **CRITICAL VALUES / RED FLAGS:**

- **ANC <1,500:** ↑ infection risk → notify HCP, possible hold
- **ANC <500:** neutropenic precautions, urgent intervention
- **K^+ >5.5 + ↑ uric acid + ↑ phosphate:** 🚨 TUMOR LYSIS SYNDROME (rituximab)
- **EF drop ≥10–15% OR <50%:** 🚨 HOLD trastuzumab, notify cardiology
- **ALT/AST >3× ULN:** hepatotoxicity — hold and notify
- **Positive TB test:** MUST treat latent TB before starting biologic

7. ADMINISTRATION & SAFETY

ROUTES:

- IV infusion (most mAbs): infliximab, rituximab, trastuzumab, bevacizumab
- SubQ injection: adalimumab, omalizumab, evolocumab, dupilumab
- NEVER given PO — mAbs are proteins; stomach acid destroys them

INFUSION SAFETY PROTOCOL:

- Pre-medicate as ordered: acetaminophen, diphenhydramine, ± corticosteroid (↓ infusion reactions)
- First infusion: start SLOWLY, titrate up if tolerated
- Emergency equipment at bedside: O_2, epinephrine, suction, crash cart
- Monitor VS q15 min during infusion, q30 min after, then per protocol
- Stop infusion IMMEDIATELY if reaction — maintain IV access with NS
- Use in-line filter if required by drug (e.g., infliximab requires 1.2-micron filter)
- Do NOT shake vials — can denature the protein
- Bring refrigerated drug to room temp before administering

HIGH-ALERT PRECAUTIONS:

- ⚠ mAbs are HIGH-ALERT medications — use 2-nurse verification per facility policy
- ⚠ Verify correct drug — suffixes are similar (-mab); confusion with biosimilars
- ⚠ Handle as hazardous drug if oncology mAb (trastuzumab, rituximab, bevacizumab)
- ⚠ Rotate SubQ injection sites; do NOT inject into tender/red/bruised skin

8. PATIENT EDUCATION

TEACH THE PATIENT:

- AVOID crowds, sick contacts — your immune system is suppressed
- Practice meticulous hand hygiene; use soft toothbrush; avoid sharing utensils
- NO live vaccines (MMR, varicella, yellow fever, FluMist) during therapy
- Inactivated vaccines (Tdap, flu shot IM, pneumococcal) usually OK — confirm with HCP
- Do NOT stop the drug abruptly — even if feeling well (autoimmune flare)
- Effects may take weeks to months — be patient
- Use effective contraception during therapy and for months after (varies by drug)
- Store biologics in refrigerator (do NOT freeze); bring to room temp before SubQ
- Rotate SubQ injection sites (abdomen, thigh, upper arm)
- Keep infusion appointments — missing doses ↓ effectiveness and ↑ antibody formation

🚑 CALL HCP / 911 IMMEDIATELY FOR:

- Fever ≥100.4°F (38°C), chills, productive cough, burning with urination, wound drainage
- Shortness of breath, chest pain, swollen ankles (heart failure — esp. trastuzumab)
- New weakness, confusion, vision changes, unsteady gait (PML)
- Yellowing of skin/eyes, dark urine, RUQ pain (hepatitis reactivation)
- Rash, hives, swelling of face/lips/tongue, difficulty breathing (anaphylaxis)
- Severe headache, mental status changes (ARIA — anti-amyloid mAbs)
- Persistent diarrhea, bloody stool (checkpoint inhibitor colitis)

9. NCLEX TEST TRAPS ⚠

COMMON TRAP QUESTIONS:

- **TRAP #1:** “Patient reports mild back pain during infusion.” → STOP the infusion first — don't slow it. Back pain can herald anaphylaxis/infusion reaction.
- **TRAP #2:** “Patient due for flu vaccine while on adalimumab.” → IM flu shot (inactivated) = OK. NASAL FluMist (live) = contraindicated.
- **TRAP #3:** “Patient on rituximab develops ↑ K^+, ↑ phosphate, ↓ Ca^{2+}.” → This is TUMOR LYSIS SYNDROME, not routine lab shift. Priority = cardiac monitoring + hydration + rasburicase.
- **TRAP #4:** “Patient with RA on infliximab reports cough and night sweats.” → Think TB REACTIVATION before bronchitis.
- **TRAP #5:** “Trastuzumab patient with new SOB and ankle edema.” → CARDIOTOXICITY / HF — hold drug, notify provider, get ECHO.
- **TRAP #6:** “Which is the priority action if PPD positive before starting biologic?” → Treat latent TB FIRST. Do not give the biologic yet.
- **TRAP #7:** Students confuse MOA of mAbs vs ACE inhibitors vs statins. mAbs are PROTEINS given IV/SubQ — never PO.
- **TRAP #8:** “Patient says drug isn't working after 2 weeks.” → Autoimmune mAbs take WEEKS–MONTHS. Teach patience; don't stop.

- **TRAP #9:** Natalizumab patient with new confusion and weakness → think PML, not MS flare. Requires MRI + JC virus testing.
- **TRAP #10:** PRIORITY vs non-priority — airway always wins. In an infusion reaction, first assess ABC → then stop infusion → then call HCP.

10. MEMORY BOOSTERS

SUFFIX PATTERN (ALL mAbs end in -MAB):

- **-o-MAB:** mouse origin (high allergy risk — rarely used now)
- **-xi-MAB:** chimeric (mouse + human) — e.g., rituxi-mab, inflixi-mab
- **-zu-MAB:** humanized — e.g., trastuzu-mab, bevacizu-mab, omalizu-mab
- **-u-MAB:** fully human — lowest allergy risk — e.g., adalim-u-mab, evolo-cu-mab

MNEMONIC: "B.I.O.L.O.G.I.C" (Before Starting Any mAb)

- B — Baseline labs (CBC, LFTs, EF)
- I — Infection screen (TB, Hep B/C)
- O — Observe for infusion reaction
- L — Live vaccines: NONE
- O — Ongoing monitoring
- G — Give premedications as ordered
- I — Immunosuppression teaching
- C — Contraception counseling

MNEMONIC: "R.A.S.H" (Infusion Reaction Actions)

- R — Recognize early signs (flushing, itching, SOB)
- A — Arrest the infusion (STOP immediately)
- S — Stay with patient, assess ABC, call for help
- H — Hand over: notify HCP, document, prepare epi/diphenhydramine

QUICK RECALL TRICKS:

- **"mAbs make you Sick" —** immunosuppression → infection is #1 risk
- **"Ritux = B-cell Bust" —** rituximab kills CD20 B-cells → lymphoma, RA, TLS risk
- **"Trastu = Heart Trouble" —** trastuzumab → cardiotoxicity → monitor EF
- **"Beva = Bleed + Break" —** bevacizumab → bleeding, GI perforation, poor wound healing
- **"Natali = Neuro Nightmare" —** natalizumab → PML

11. MOST TESTED mAbs — KEY DIFFERENCES

DRUG	TARGET	USE	#1 NCLEX RISK	KEY MONITOR
Rituximab	CD20	Lymphoma, RA	Tumor lysis syndrome, infusion reaction, Hep B reactivation	CBC, K^+, phosphate, uric acid, Hep B
Trastuzumab	HER2	HER2+ breast CA	Cardiotoxicity — ↓ EF, heart failure	Baseline + q3mo ECHO/MUGA, EF
Infliximab	TNF-α	RA, Crohn's, UC, psoriasis	TB reactivation, serious infections, HF	PPD before start, CBC, LFTs, infection s/sx

Adalimumab	TNF-α	RA, Crohn's, psoriasis	🚨 Infection, TB/Hep B reactivation, lymphoma	PPD, CBC, injection site, infection
Bevacizumab	VEGF	Colon, lung, brain CA	🚨 Bleeding, GI perforation, HTN, poor healing	BP, H&H, s/sx bleeding, hold 28d pre-op
Omalizumab	IgE	Severe allergic asthma	🚨 Anaphylaxis (can be delayed up to 24h)	Observe 2h post-injection, EpiPen teaching
Natalizumab	α4-integrin	MS, Crohn's	🚨 PML (fatal brain infection)	JC virus Ab, q6mo MRI, neuro status
Tocilizumab	IL-6	RA, CRS, giant cell arteritis	🚨 Serious infection, GI perforation, ↑ LFTs	CBC, LFTs, lipids, infection
Evolocumab / Alirocumab	PCSK9	Refractory ↑ LDL, FH	🚨 Injection site reaction, rare hypersensitivity	LDL q4–12 weeks (target ↓50%+)
Pembrolizumab / Nivolumab	PD-1	Melanoma, lung CA, many solid tumors	🚨 Immune-related AEs: colitis, pneumonitis, hepatitis, endocrinopathies	LFTs, TSH, cortisol, lung/GI sx
Palivizumab / Nirsevimab	RSV F-protein	RSV prevention in infants	🚨 Rare anaphylaxis — monthly IM during RSV season	Injection site, breathing
Lecanemab / Aducanumab	Amyloid-β	Early Alzheimer's	🚨 ARIA — brain edema / microhemorrhages	Serial MRI, neuro status, HA/confusion

🚨🧠. CLINICAL JUDGMENT SNAPSHOT — NCJMM PRIORITIES

❓ What is the #1 PRIORITY RISK with monoclonal antibodies?

- 👉 **INFUSION REACTION / ANAPHYLAXIS** (highest during FIRST dose) **AND SERIOUS INFECTION** from immunosuppression (TB reactivation, sepsis, opportunistic infection).

❓ What will HARM the patient FIRST?

- 👉 **AIRWAY compromise from anaphylaxis** (bronchospasm, angioedema) — within minutes of infusion start. Always A-B-C priority.
- 👉 **Class-specific first harms:** Rituximab → tumor lysis (hyperkalemia → cardiac arrest). Trastuzumab → acute heart failure. Natalizumab → PML. Bevacizumab → hemorrhage/GI perforation.

❓ What is the FIRST NURSING ACTION?

- 👉 **STOP the infusion immediately** at first sign of reaction (flushing, SOB, back pain, itching, hypotension).
- 👉 **Then:** Maintain IV access with NS → Assess ABC → Apply O_2 → Call rapid response → Prepare epinephrine, diphenhydramine, corticosteroids → Stay with patient.
- 👉 **BEFORE first dose:** Verify TB screen, Hep B status, baseline labs, premedications, and emergency equipment at bedside.

🔑 **NCLEX GOLDEN RULE: AIRWAY → BREATHING → CIRCULATION → STOP THE INFUSION → NOTIFY HCP**