Advancing Kidney Health
Through Optimal Medication Management

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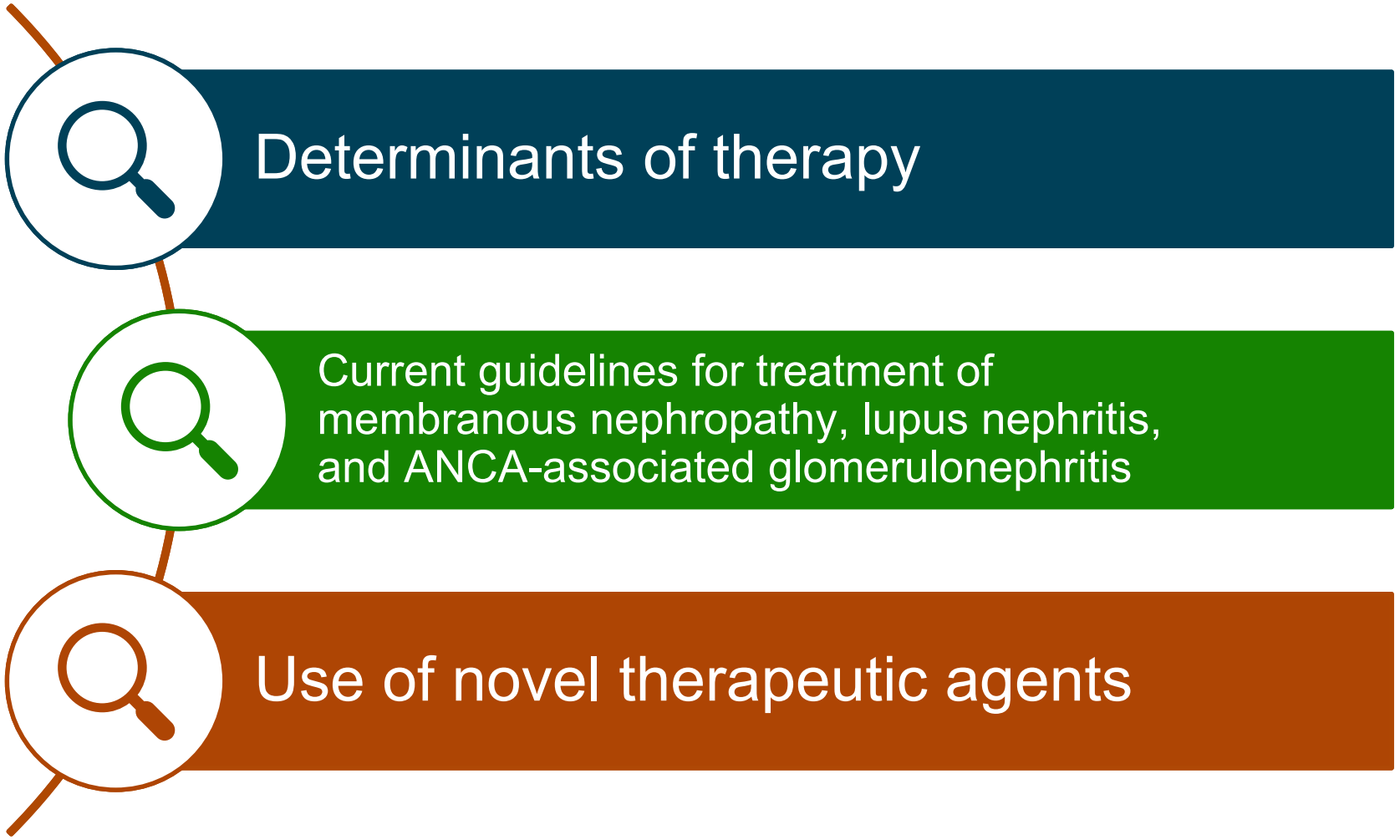
# Primer on Immunosuppressants used in Glomerular Disease

## Part 2: Indications and Novel Agents

# What We're Going to Cover:

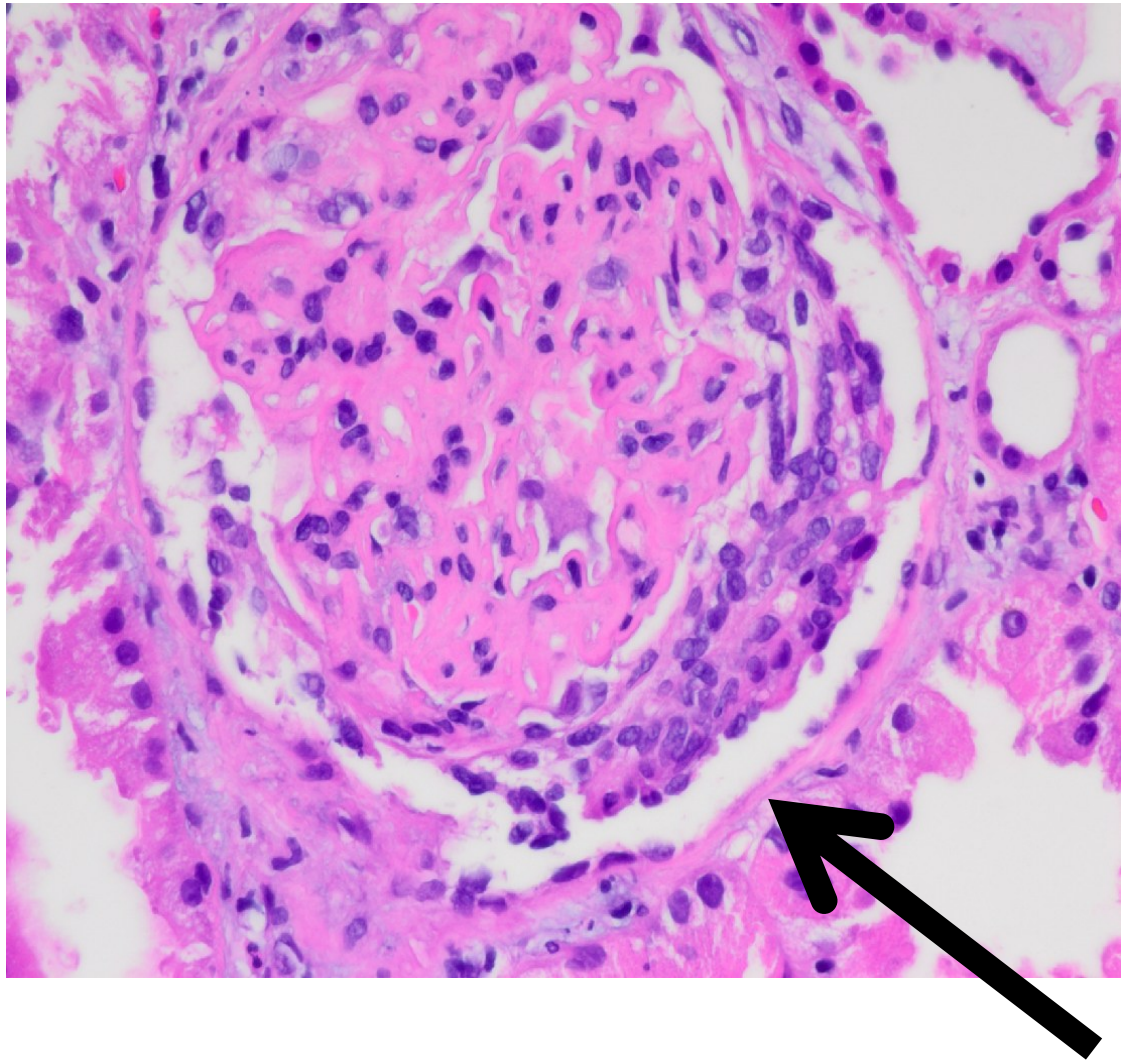


# Glossary of Terms


- **ACR** = American College of Rheumatology
- **ANCA** = Anti-neutrophil cytoplasmic antibody
- **AntidsDNA Ab** = anti-double stranded DNA antibody
- **C3** = Complement 3
- **C4** = Complement 4
- **CKD** = Chronic kidney disease
- **CRR** = Complete renal response
- **ESRD** = End-stage renal disease
- **EULAR** = European Alliance of Associations for Rheumatology
- **FDA** = Food and Drug Administration
- **GFR** = glomerular filtration rate, either estimated (e) or measured (m)
- **GLP-1** = Glucagon-like-peptide 1
- **KDIGO** = Kidney Disease Improving Global Outcomes
- **MRA** = Mineralocorticoid receptor antagonists
- **NSAIDs** = Nonsteroidal anti-inflammatory drugs
- **PCP** = Primary care provider
- **PLA2R ab** = phospholipase A2 receptor antibody
- **RAS inhibition** = Renin Angiotensin System
- **sAlbumin** = serum albumin
- **sCr** = serum creatinine
- **SGLT-2i** = sodium glucose co-transporter 2 inhibitor
- **UPC** = urine protein to creatinine ratio
- **USRDS** = United States Renal Data System

# Why Does it Matter?

- **Glomerular disease** is a leading cause of cause of chronic kidney disease (CKD) and end-stage renal disease (ESRD)
- **Glomerulonephritis** is the cause of ESRD in 15% of patients in the US Renal Data System (USRDS)
- **Patients with nephrotic syndrome due to glomerular disease experience** reduced health related quality of life with scores similar to patients on dialysis



CDC.gov/kidney-disease; PLoS One 2012; 7(5): e37763

## Determinants of Therapy

Kidney biopsy findings

Kidney function at time of biopsy and during follow up

Degree of proteinuria

# Case Scenario 1: Introduction

| Patient |
| --- |
| 35 year-old female presents with nephrotic syndrome. She has noted swelling of her legs to the level of her thighs and has gained about 20 pounds over the last 3-4 weeks.<br><br>Allergies: NKDA |

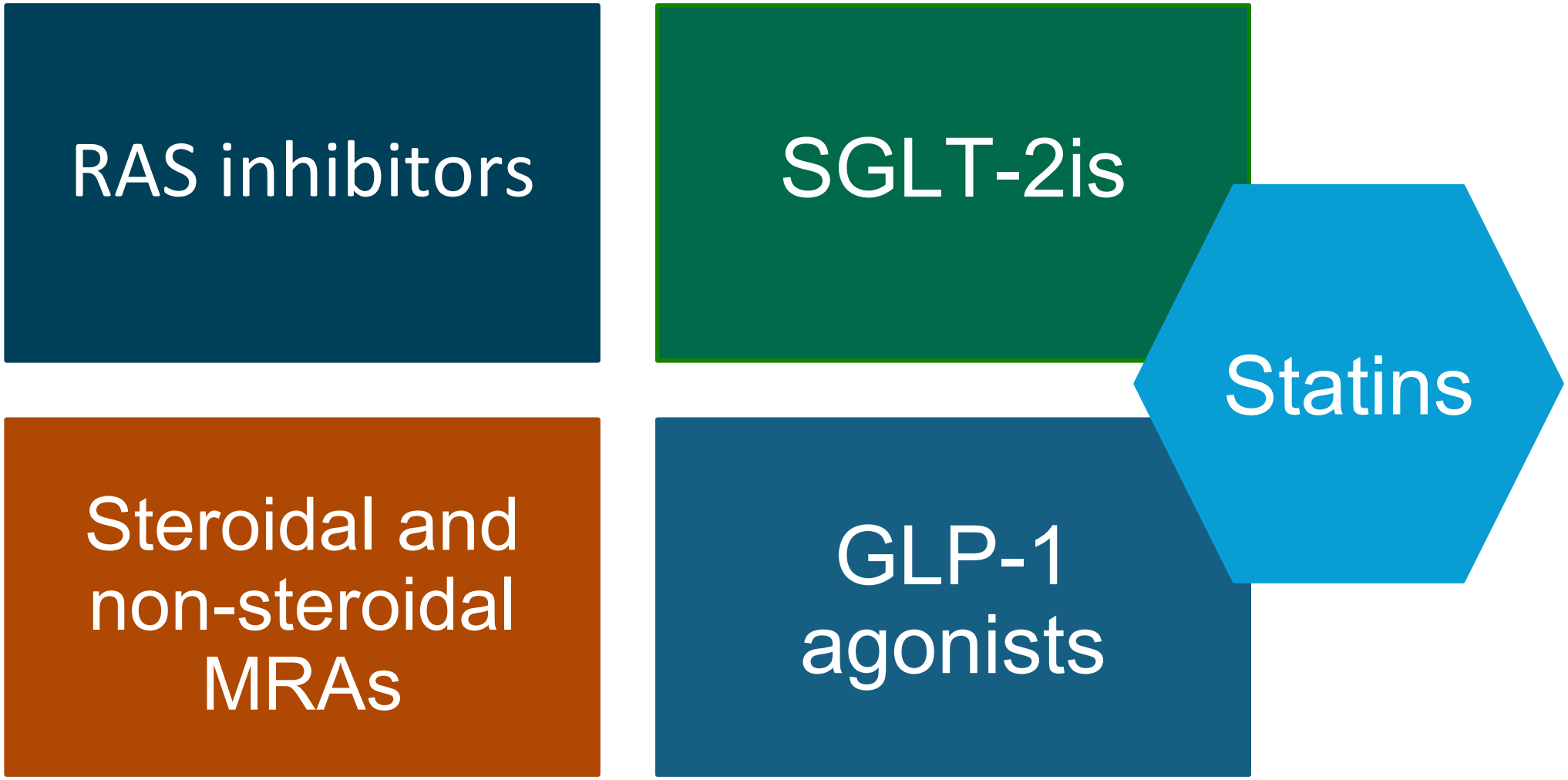
| Medications | |
| --- | --- |
| Chlorthalidone | 25 mg po daily |
| Metformin | 500 mg po bid |
| Sertraline | 50 mg po daily |

| PMH | |
| --- | --- |
| Hypertension | |
| Glucose intolerance | |
| Depression | |

**Labs/Vitals**

| Vital | Today | 1 mo ago | 6 mos ago |
| --- | --- | --- | --- |
| Height (in) | 63 | | |
| Weight (lbs) | 170 | 150 | 150 |
| **Lab** | **Today** | **1 mo ago** | **6 mos ago** |
| sCr | 1.0 | 0.9 | 0.9 |
| sAlbumin | 2.5 | 3.8 | 4.0 |
| UPC | 4.5 | | |
| PLA2R Ab | Pending | | |
| Pregnancy Test | Negative | | |

# Non-immunosuppressant Therapies Used in Setting of Proteinuric Kidney Diseases



# Case Scenario 1: Patient Results

## Kidney Biopsy, Renal Function, Testing, and Consult Results

- Kidney biopsy consistent with membranous nephropathy
- Normal eGFR
- UPC > 3.5
- Anti-PLA2R antibodies 120 RU/ml
- No evidence of infection, lupus, malignancy, or use of NSAIDs

What do we do?

# Risk Stratification for Membranous Nephropathy

## Low Risk

- Normal kidney function
- Lower levels of proteinuria (<3.5 g/day), and serum albumin >3 g/dl

OR

- Normal eGFR, proteinuria <3.5 g/d or a decrease >50% after 6 months of conservative therapy with ACEi/ARB

## Moderate Risk

- Normal eGFR with proteinuria >3.5 g/d and no decrease >50% after 6 months of conservative therapy with ACEi/ARB

AND

- Not fulfilling high-risk criteria

## High Risk

- eGFR <60 ml/min/1.73$^2$ and/or proteinuria >8 g/d for >6 months

OR

- Normal eGFR, proteinuria >3.5 g/d and no decrease >50% after 6 months of conservative therapy with ACEi/ARB

AND at least one of the following:

- Serum albumin <2.5 g/dl
- PLA2Rab >50 RU/ml
- Urinary $a_1$–microglobulin >40 µg/min
- Urinary $\beta_2$–microglobulin >250 mg/d
- Selectivity index >0.20

## Very High Risk

- Life-threatening nephrotic syndrome

OR

- Rapid deterioration of kidney function not otherwise explained

KDIGO 2021 Guidelines for Glomerular Disease

# Case Scenario 1: Management of Membranous Nephropathy

## At Time of Diagnosis

- Normal eGFR → low risk
- UPC > 3.5 → increased risk
- Positive anti-PLA2R antibodies at time of diagnosis → neutral risk
- CONSERVATIVE THERAPY with RAS inhibition
- Diuretics for edema, management of hyperlipidemia, and consideration of anticoagulation

## 6 Months Later

- Normal eGFR
- UPC still 4.5
- sAlbumin 2.3
- Anti-PLA2R Ab 152
- What's next

# Case Scenario 1: Membranous Nephropathy Next Steps

## Membranous Nephropathy Risk Evaluation

### Low Risk
- Wait and see

### Moderate Risk
- Wait and see
- OR rituximab
- OR calcineurin inhibitor ± glucocorticoids

### High Risk
- Rituximab
- OR cyclophosphamide + glucocorticoids
- OR calcineurin inhibitor + rituximab

### Very High Risk
- Cyclophosphamide + glucocorticoids

KDIGO 2021 Guidelines for Glomerular Disease

# Rituximab: What it is and FDA Approval

## What is it?

- Chimeric mouse/human monoclonal antibody
- Binding specificity to CD20 which expressed on surface of developing B cells resulting in cell destruction
- First therapeutic antibody approved for oncology patients and has improved outcomes in B-cell malignancies
- Causes reductions in serum immunoglobulin levels
- Can cause fatal, infusion-related reactions

## FDA Approval

- Initial FDA approval in 1997
- Not FDA approved for membranous nephropathy or lupus nephritis
- FDA approved for granulomatosis with polyangiitis and microscopic polyangiitis

# Recommended Dosing for Membranous Nephropathy

| Medication | Dosage |
|---|---|
| Cyclophosphamide (cyclical) | • Methylprednisolone 1 g i.v. for 3 consecutive days at start of month 1, 3, & 5<br>• Prednisone: 0.5 mg/kg/d in month 1, 3, & 5<br>• Cyclophosphamide 2.5 mg/kg/d in months 2, 4, & 6 |
| Cyclophosphamide (continuous) | • Methylprednisolone 1 g i.v. for 3 consecutive days at start of month 1, 3, & 5<br>• Prednisone: 0.5 mg/kg/d in month 1-6, with taper thereafter<br>• Cyclophosphamide 1.5 mg/kg/d in months 1-6 |
| Rituximab | • Rituximab 1 g i.v. administered twice within 2 weeks<br>• Rituximab 375 mg/$m^2$ given 1-4 times at weekly intervals |
| Tacrolimus | • Tacrolimus 0.05-0.1 mg/kg/d, target trough level 3-8 ng/ml (3.7-9.9nmol/l), duration 12 months |
| Cyclosporine | • Cyclosporine 3.5 mg/kg/d, target trough level 125-225 ng/ml (104-187 nmol/l) |

KDIGO 2021 Guidelines for Glomerular Disease

# Which of the following factors are considered high risk in the setting of membranous nephropathy?

a. **eGFR <60 ml/min/1.73m$^2$ and proteinuria >8 g/day for greater than 6 months.**
**Correct.** Abnormal renal function and proteinuria greater than 8 g/day for greater than 6 months is considered high risk disease and treatment with rituximab or cyclosporine plus glucocorticoids should be given. A second treatment option in this setting would rituximab plus a calcineurin inhibitor.

b. Normal eGFR and proteinuria >3.5 g/day with no decrease >50% after 6 months of conservative therapy with ACEi or ARB.
Incorrect. These two factors would be considered high risk only with the addition of a third factor such as serum albumin less than 2.5 g/dl or anti-phospholipase A2 receptor antibodies greater than 50 RU/ml.

c. Serum albumin greater than 3 g/dL.
Incorrect. Serum albumin levels greater than 3 would be considered low risk as long as renal function is also normal.

d. Anti-phospholipase A2 receptor antibody level greater than 50 RU/ml at time of diagnosis.
Incorrect. Elevated anti-phospholipase A2 receptor antibody level is a highly specific biomarker for primary membranous nephropathy and may be measured serially to monitor response to therapy but is not predictive of progressive disease at the time of diagnosis.

# Case Scenario 2: Introduction

| Patient |
| --- |
| 35 year-old female presents with nephrotic syndrome. She has noted swelling of her legs to the level of her thighs and has gained about 20 pounds over the last 3-4 weeks.<br><br>Allergies: NKDA |

| Medications | |
| --- | --- |
| Chlorthalidone | 25 mg po daily |
| Metformin | 500 mg po bid |
| Sertraline | 50 mg po daily |

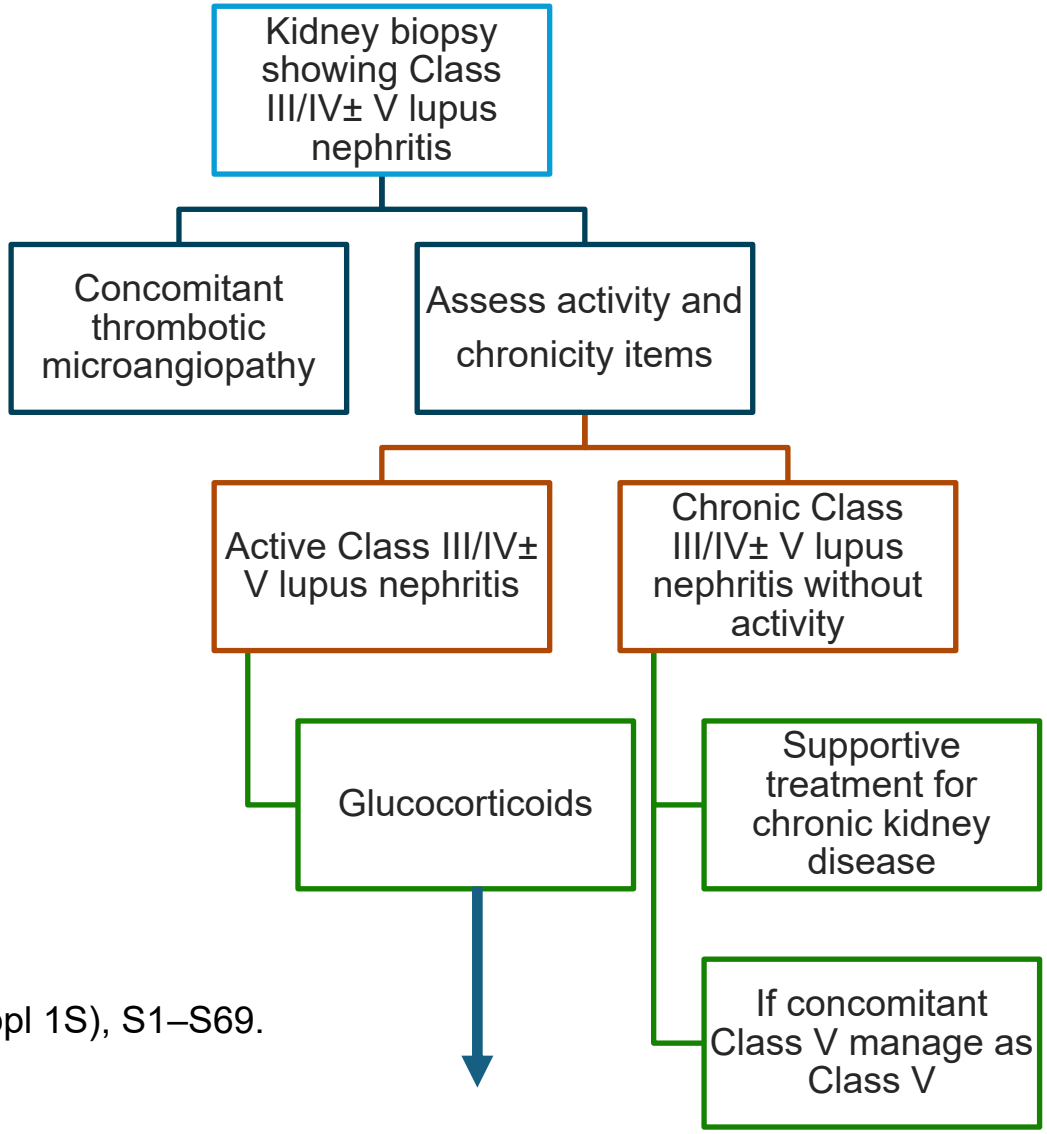
| PMH | |
| --- | --- |
| Hypertension | |
| Glucose intolerance | |
| Depression | |

Renal biopsy consistent with class IV/V lupus nephritis with active disease

**Labs/Vitals**

| Vital | Today | 1 mo ago | 6 mos ago |
| --- | --- | --- | --- |
| Height (in) | 63 | | |
| Weight (lbs) | 170 | 150 | 150 |
| **Lab** | **Today** | **1 mo ago** | **6 mos ago** |
| sCr | 1.0 | 0.9 | 0.9 |
| sAlbumin | 2.5 | 3.8 | 4.0 |
| UPC | 4.5 | | |
| PLA2R Ab | Negative | | |
| C3 | 55 | | |
| C4 | 10 | | |
| antidsDNA Ab | 80 | | |
| Pregnancy test | Negative | | |

# KDIGO 2024 Treatment Guidelines Pt 1




Kidney International (2024) 105 (Suppl 1S), S1–S69.

# KDIGO 2024 Treatment Guidelines Pt 2

Glucocorticoids

Methylprednisolone i.v. 0.25-0.50 g/d for 1-3 days as appropriate depending on disease severity and rate of progression, then prednisone p.o. at approximately 0.35-1.0 mg/kg/d (not to exceed 80 mg/d) and taper over a few months to maintenance dose (the lower steroid dosing option referring to the reduced-dose regimen in the voclosporin trials)

CNI+MPAA

Voclosporin 23.7 mg b.i.d. and MPAA in patients with eGFR >45 ml/min per 1.73 $m^2$

Tacrolimus (trough level approximately 5.5 ng/ml [6.8 nmol/l], data mainly from Chinese patients) and reduced-dose MPAA in patients with SCr <3.0 mg/di (265 µmol/1) as initial and maintenance therapy

Consider cyclosporine when voclosporin and tacrolimus are not available.

CNI duration up to 3 years

Mycophenolic acid analogs (MPAA) for at least 6 months MMF p.o. 1.0-1.5 g b.i.d. or mycophenolic acid sodium 0.72-1.08 g b.i.d.

Cyclophosphamlde for up to 6 months i.v. 500 mg q2wk x 6 or 05-1.0 g/$m^2$ monthly x 6; or p.o. 1.0-1.5 mg/kg/d for 3 months

Belimumab + MPAA or reduced-dose cyclophosphamide Belimumab (i.v., 10 mg/kg q2wk for 3 doses then q4wk) and MPAA or i.v. cyclophosphamide 500 mg q2wk x 6 Belimumab duration up to 2.5 years

Kidney International (2024) 105 (Suppl 1S), S1–S69.

# American College of Rheumatology 2024 Lupus Nephritis Guideline-Treatment Overview Pt 1

| Class III/IV ± V<br>*Active, newly diagnosed or flare* | Pure Class V<br>*Active, newly diagnosed or flare* |
|---|---|
| Hydroxychloroquine and RAAS-I | |
| **First Line (Continuous) Therapy**<br>***Preferred*:**<br>TRIPLE THERAPY<br>GC pulse/oral taper to ≤ 5mg/day by 6 mo.<br>+ MPAA + BEL *or* CNI | **First Line (Continuous) Therapy**<br>***Preferred*:**<br>TRIPLE THERAPY<br>GC pulse/oral taper to ≤ 5mg/day by 6 mo.<br>+ MPAA + CNI |
| ***Alternatives:***<br>TRIPLE THERAPY<br>GC pulse/oral taper to ≤ 5mg/day by 6 mo.<br>+ Low-dose CYC + BEL | ***Alternatives:***<br>TRIPLE THERAPY<br>GC pulse/oral taper to ≤ 5mg/day by 6 mo.<br>+ MPAA + BEL or Low-dose CYC + BEL |
| Dual therapy if triple therapy is not available or tolerated | Dual therapy if triple therapy is not available or tolerated |

**Lack of Response**

https://acrjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/art.43212

# American College of Rheumatology 2024 Lupus Nephritis Guideline-Treatment Overview Pt 2

## Lack of Response

**IF INITIAL TRIPLE THERAPY:**
Change to Alternative Triple Therapy

**IF INITIAL DUAL THERAPY:**
Escalate to Triple Therapy

## Refractory Disease

- **Consider** adherence and/or other diagnoses (e.g. aPL nephropathy) OR advanced chronicity
- **Escalate** to a more intensive regimen, including:
  - Addition of anti-CD20 agents, combination therapy with 3 immunosuppressives (i.e, MAPP, belimumab and CNI) OR
  - Referral for investigational therapy

## Goal

- **Complete renal response (CRR):**
  - Within 6-12 mo., reduction in proteinuria to $\leq$0.5 g/g and
  - Stabilization or improvement in kidney function ($\pm$20% baseline)
- **Duration of therapy:**
  - At least 3-5 years achievement of CRR

https://acrjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/art.43212

# What is new in the treatment of lupus nephritis?

**Focus on reduction in corticosteroid exposure**

## Belimumab

- Fully human monoclonal antibody targeting soluble B-lymphocyte stimulator (BlyS or BAFF)
- Results in reduced survival of autoreactive B cells and decreased autoantibody production

## Voclosporin

- Novel oral calcineurin inhibitor which results in suppression of T cell activation
- Does not require therapeutic drug monitoring
- Avoid use if eGFR ≦ 45 ml/min/1.73m2

Benlysta FDA Drug Label; Medicine 2025; 104(25): 42858; Kidney International. 2024;105(1S):S1-S69.

# BLISS-LN Trial

## Belimumab International Study in Lupus Nephritis

- Phase 3 multicenter, randomized, double-blind, placebo-controlled 2-year trial:
  - Compared the efficacy and safety of intravenous belimumab with those of placebo, plus standard therapy, in patients with active lupus nephritis
- 448 patients underwent randomization (224 to the belimumab group and 224 to the placebo group).
- At week 104 (2 yrs), significantly more patients in the belimumab group than in the placebo group had:
  - A primary efficacy renal response (43% vs. 32%; odds ratio, 1.6; 95% confidence interval [CI], 1.0 to 2.3; P = 0.03)
  - And a complete renal response (30% vs. 20%; odds ratio, 1.7; 95% CI, 1.1 to 2.7; P = 0.02).
- The risk of a renal-related event or death was lower among patients who received belimumab than among those who received placebo (hazard ratio, 0.51; 95% CI, 0.34 to 0.77; P = 0.001)

N Engl J Med. 2020; 383(12):1117-1128.

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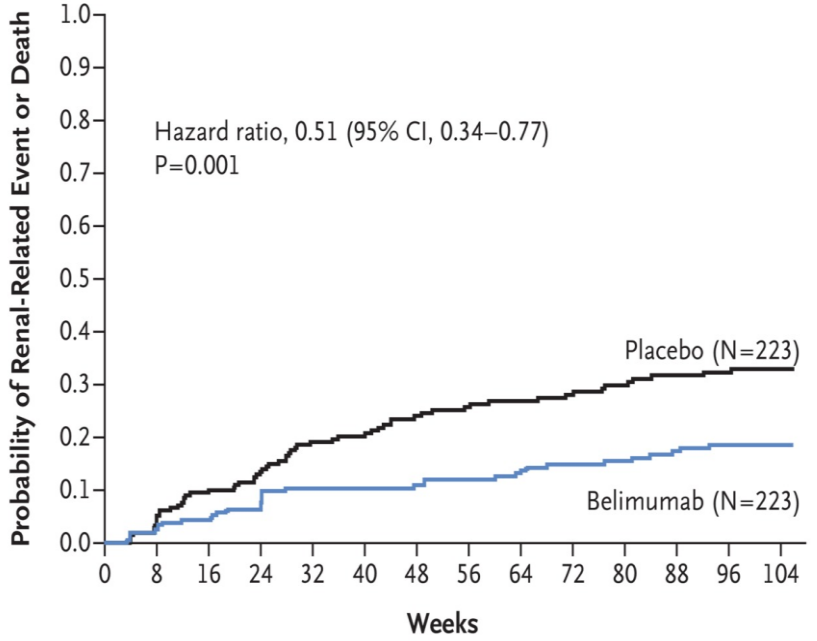


**No. at Risk**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Placebo | 203 | 185 | 175 | 154 | 147 | 137 | 129 | 126 | 120 | 116 | 112 | 110 | 78 |
| Belimumab | 209 | 192 | 186 | 167 | 162 | 159 | 157 | 151 | 142 | 139 | 133 | 130 | 102 |

B

| Event | Belimumab (N=223) | Placebo (N=223) |
|---|---|---|
| | *no.* | |
| Any event | 35 | 63 |
| Death from any cause | 1 | 2 |
| Progression to ESKD | 0 | 1 |
| Doubling of creatinine level from baseline | 1 | 1 |
| Increased proteinuria, impaired kidney function, or both | 17 | 39 |
| Treatment failure related to kidney event | 16 | 20 |

# Voclosporin in AURA-LV and AURORA 1

- Voclosporin 23.7 mg twice daily in combination with mycophenolate mofetil (MMF) and oral glucocorticoids in lupus nephritis
- 534 patients (268 voclosporin; 266 control) were included; used pooled data from AURA-LV and AURORA 1
- More patients achieved a CRR at one year in the voclosporin group than in the control group (43.7% vs. 23.3%; OR 2.76; 95% CI 1.88-4.05; $P < 0.0001$).
- Incidence of adverse events (AEs) was similar (91.4% voclosporin; 87.2% control)

Arthritis Care & Research 75 (7): 1399-1408, 2023.

# Obinutuzumab: The new kid on the block

## What is it?

- Humanized anti-CD20 monoclonal antibody of the IgG1 subclass
- Targets the CD20 antigen expressed on the surface of pre-B and mature B lymphocytes
- Results in B-cell lysis
- Has greater antibody cellular cytotoxicity than rituximab
- Indicated for use on chronic lymphocytic leukemia, follicular lymphoma, and for adult patients with active lupus nephritis on standard therapy

## REGENCY Trial

- Phase 3 randomized, double-blind placebo-controlled trial
- Adults with biopsy-proven class III or IV (with or without class V) lupus nephritis on MMF and prednisone
- Obinutuzumab 1000 mg IV on day 1, weeks 2, 24, 26, and 52 or placebo
- Complete renal response at week 76 was 46.4% for treatment group versus 33.1% for placebo (p=0.02).

N Engl J Med. 2025; 392(15):1471-1483.

# Case Scenario 3: Introduction

| Patient |
| --- |
| 35 year-old female presents with malaise, fever, and decreased appetite. She has noted pedal edema. She reports that her urine is tea-colored. Her blood pressure has been higher.<br><br>Allergies: NKDA |

| Medications | |
| --- | --- |
| Chlorthalidone | 25 mg po daily |
| Metformin | 500 mg po bid |
| Sertraline | 50 mg po daily |

| PMH | |
| --- | --- |
| Hypertension | |
| Glucose intolerance | |
| Depression | |

**Labs/Vitals**

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| **Lab** | **Today** | **1 mo ago** | **6 mos ago** |
| sCr | 3.0 | 0.9 | 0.9 |
| sAlbumin | 2.5 | 3.8 | 4.0 |
| UPC | 2 | | |
| C3 | 100 | | |
| C4 | 20 | | |
| Anti-PR3 | 8 | | |
| Pregancy test | Negative | | |

Renal biopsy consistent with granulomatosis with polyangiitis

# ANCA-associated vasculitis

Characterized by necrotizing inflammation of small vessels (arterioles, capillaries, and venules)

"Pauci-immune" as not associated with deposition of immune complexes

Include granulomatosis with polyangiitis, microscopic polyangiitis, and eosinophilic granulomatosis with polyangiitis

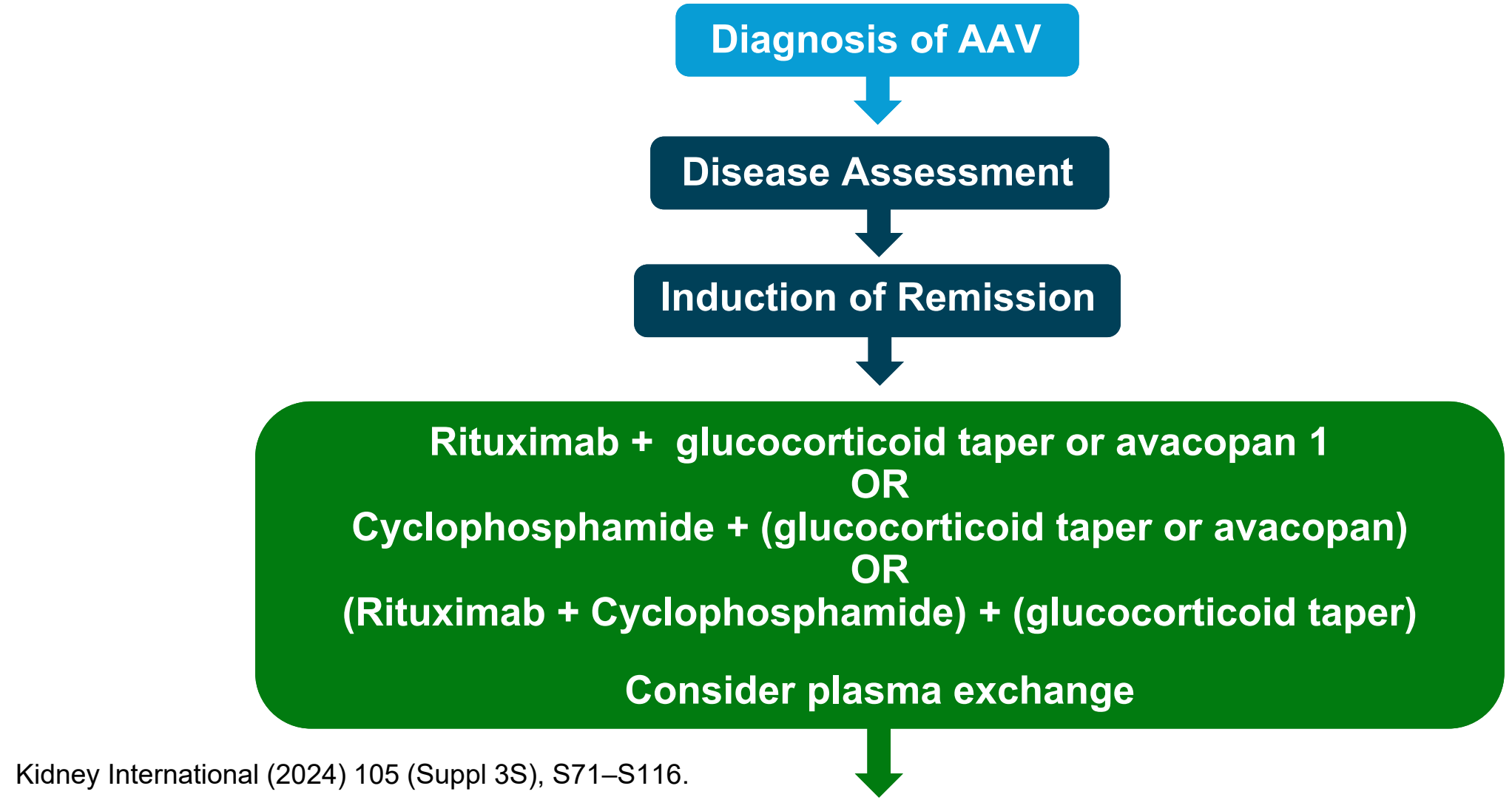
Often presents as a necrotizing and crescentic glomerulonephritis

May also involve upper and lower respiratory tract, skin, eyes, and the nervous system

Pulmonary hemorrhage is seen in ~10% of patients

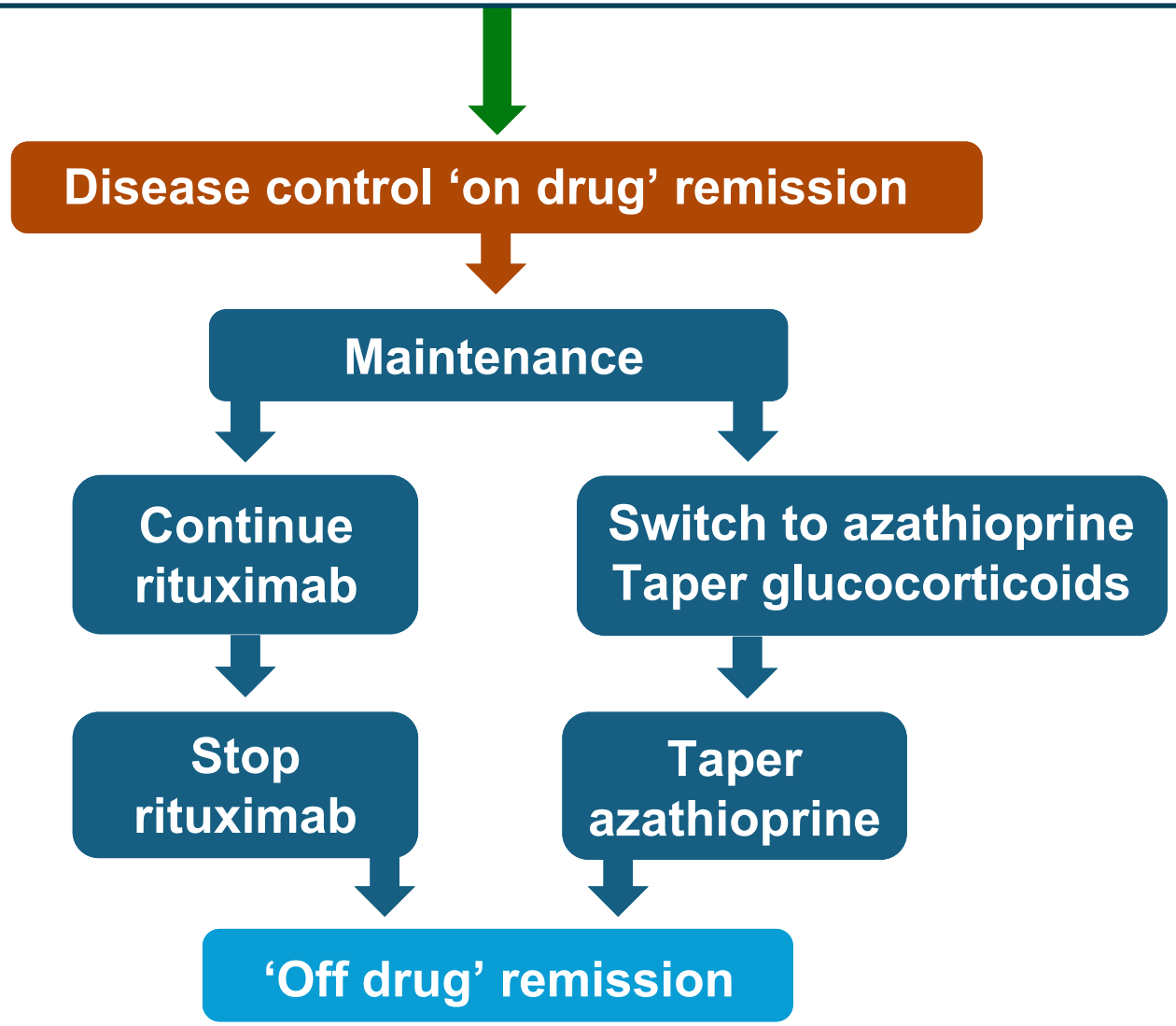
Kidney International (2024) 105 (Suppl 3S), S71–S116.

# KDIGO 2024 Guidelines: ANCA-associated Vasculitis Pt 1



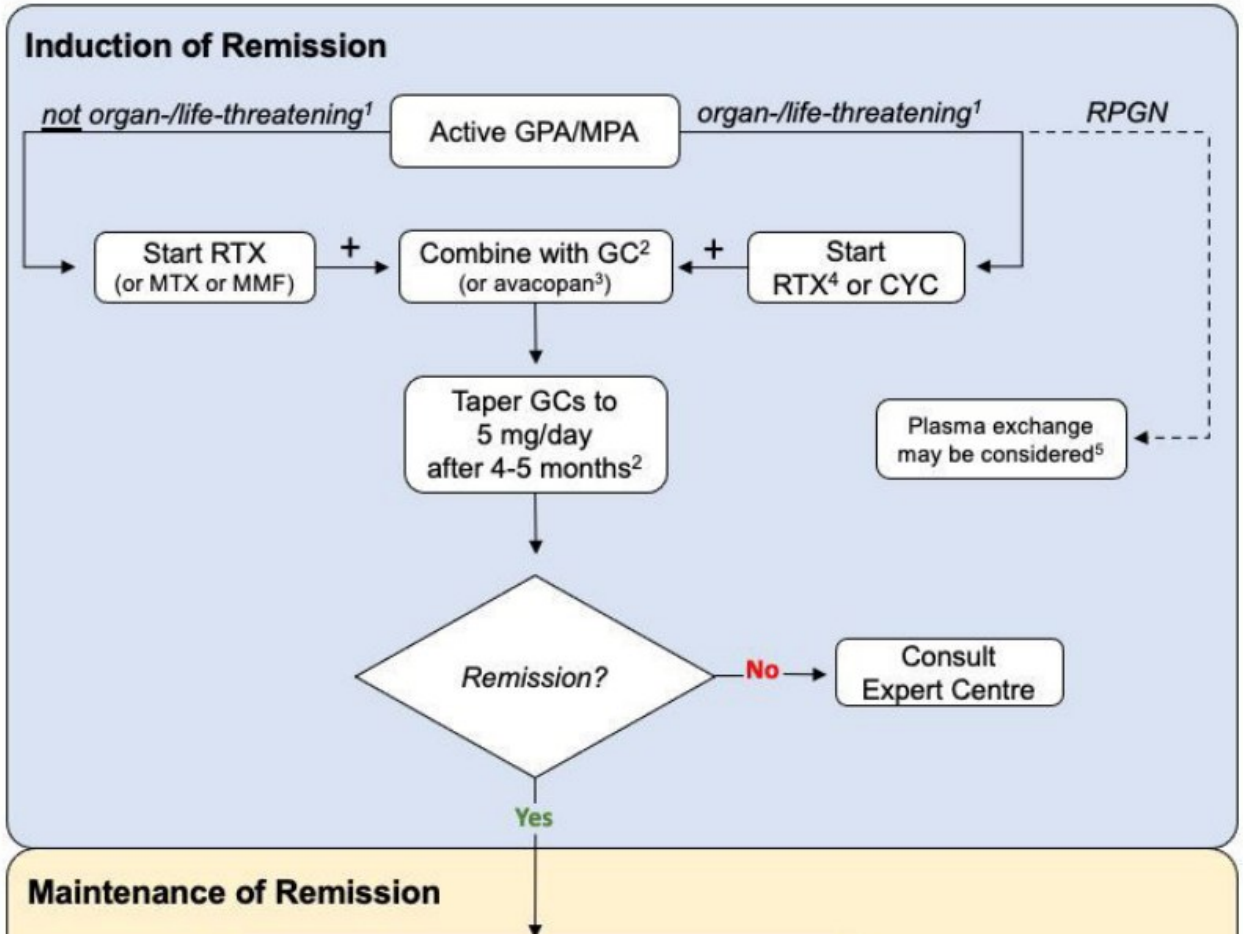

Kidney International (2024) 105 (Suppl 3S), S71–S116.

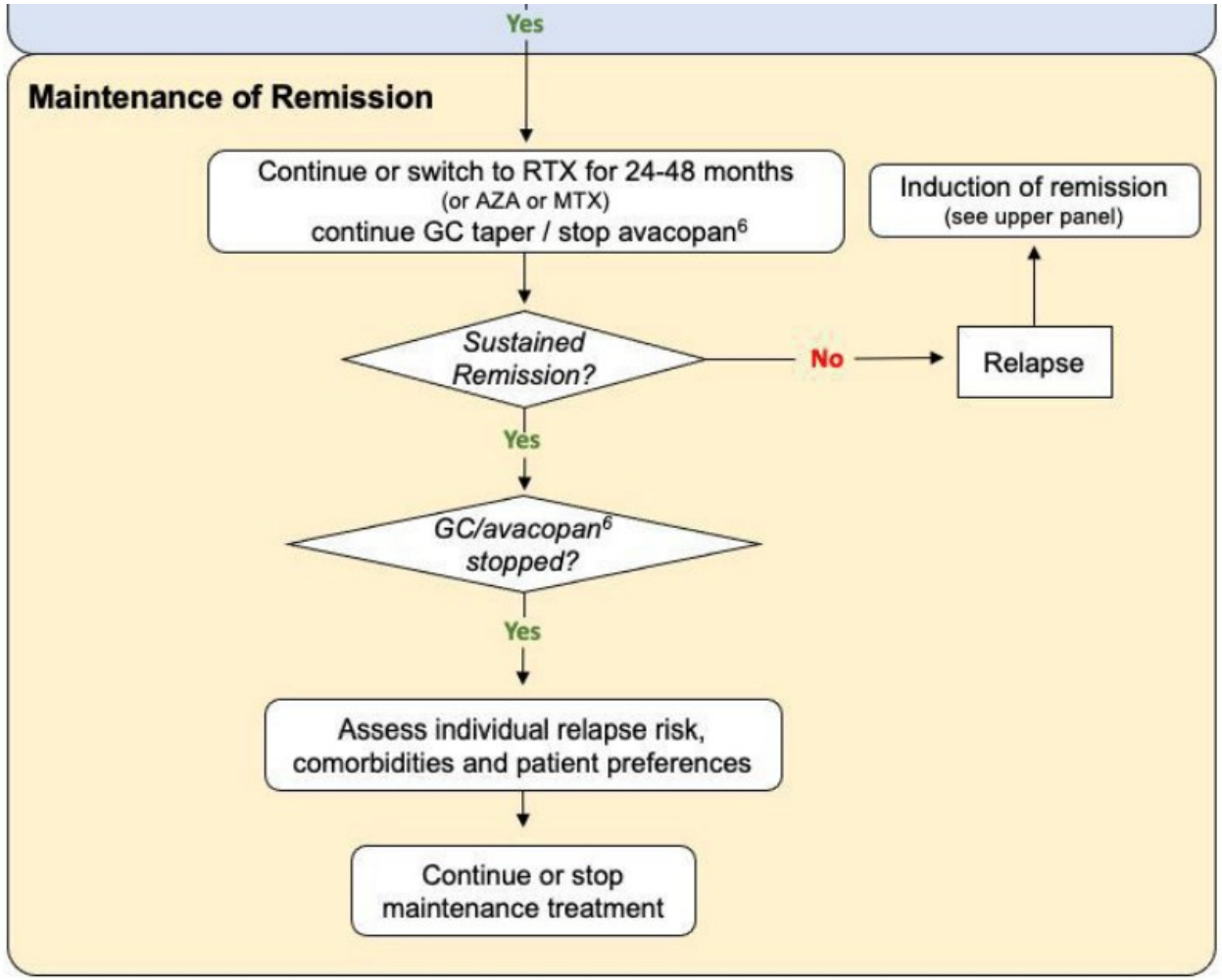
# KDIGO 2024 Guidelines: ANCA-associated Vasculitis Pt 2




Kidney International (2024) 105 (Suppl 3S), S71–S116.

# EULAR 2022




Ann Rheum Dis 2024;83:30–47.

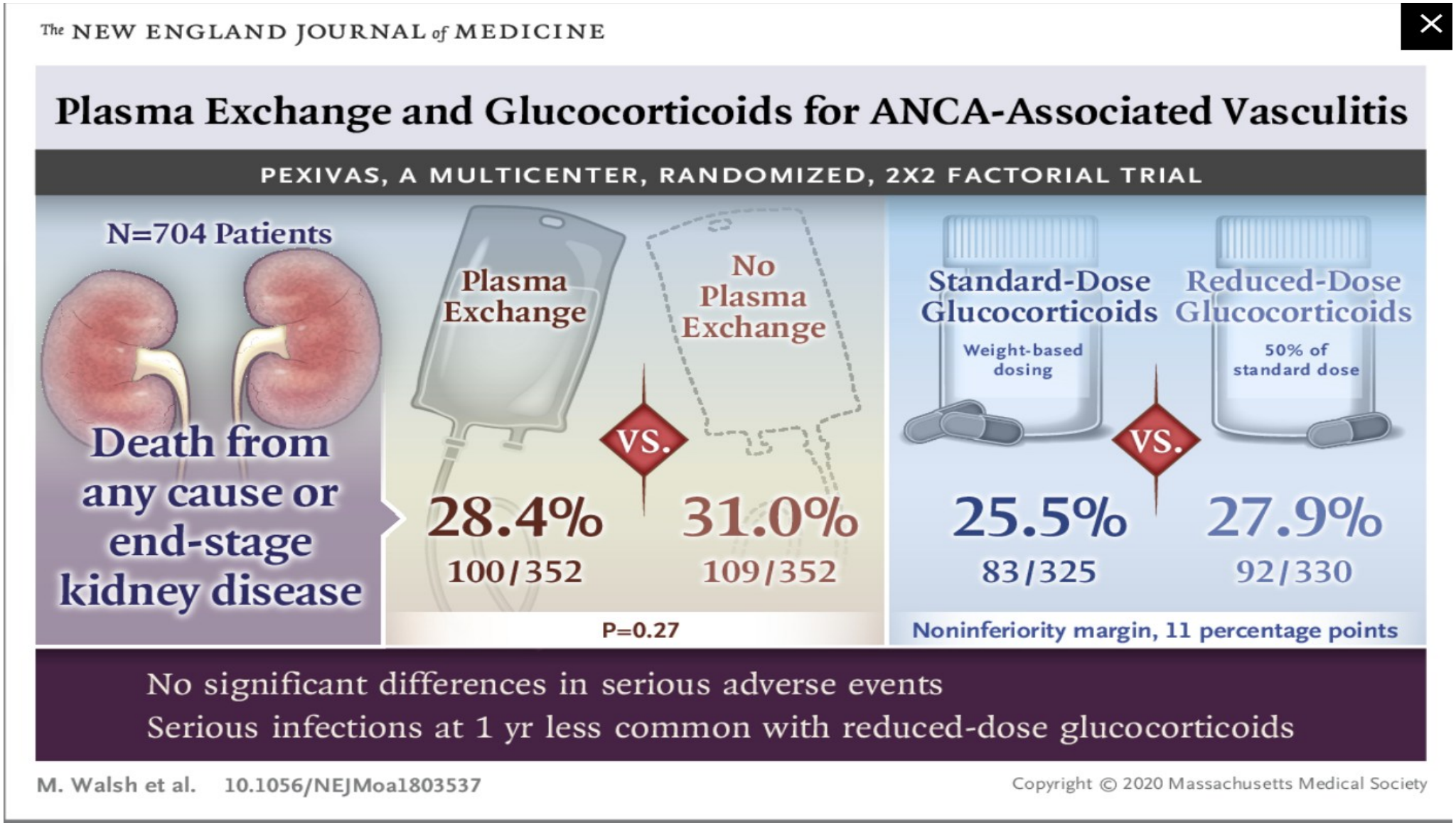
# EULAR 2024 Update

- Use glucocorticoids and rituximab or cyclophosphamide for induction
  - Rituximab is preferred in setting of relapsing disease
- Use PEXIVAS protocol for rapid tapering of glucocorticoids
- Consider plasma exchange if serum creatinine >3.4 mg/dl

- Note:
  - Fixed-interval repeat dose rituximab for 24-48 months is more effective than azathioprine or methotrexate and permits more rapid glucocorticoid discontinuation
  - Avacopan is superior over 1 year of therapy compared to a standard glucocorticoid tapering regimen when given in combination with rituximab or cyclophosphamide

Nephrol Dial Transplant, 2024, 39, 944–955.

# PEXIVAS Trial



# Avacopan and the ADVOCATE Trial

## Avacopan

- Orally administered small-molecule C5a receptor antagonist
- Blocks C5a preventing neutrophil chemoattraction and activation.

- ADVOCATE Trial
  - 331 patients randomized 1:1 to either avacopan 30 mg po bid or oral prednisone taper
  - All patients had received either cyclophosphamide or rituximab
  - Remission at week 26: 72.3% of patients on avacopan and 70.1% of patients on prednisone ($P<0.001$ for noninferiority)
  - Remission at week 52: 65.7% on avacopan and 54.9% on prednisone ($P<0.001$ for nonferiority; $P= 0.007$ for superiority)
  - Serious adverse events: 37.3% on avacopan and 39% on prednisone

N Engl J Med 2021;384:599-609.

# Steroid Resistant FSGS/MCD with Nephrotic Syndrome

- Relapse either at full-dose or during tapering or within 14 days of discontinuation of glucocorticoids
- Use glucocorticoid-sparing agents to prevent relapses
- Calcineurin inhibitors are the most frequently used steroid sparing agents in both steroid-dependent and steroid-resistant disease
- Cyclosporine is usually given at 4-5 mg/kg/day in two divided dose with target trough 60-150 ng/ml
  - May be preferred in patients at risk for diabetes
- Tacrolimus is usually started at 0.1 mg/kg/day in two divided doses with target trough 5-10 ng/ml

Kidney International (2025) 107 (Suppl 5S), S241–S289.

# Which of the following medications is NOT used as a steroid-sparing agent in the setting of glomerular disease?

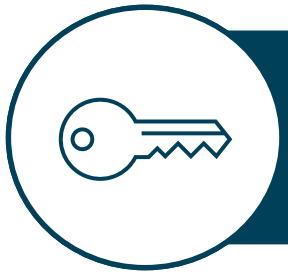
a. Avacopan.
Incorrect. In the ADVOCATE trial for ANCA-associated glomerulonephritis, patients assigned to the avacopan treatment group were not administered glucocorticoids after randomization but were compared to a group treated with prednisone tapered over 20 weeks.

b. Belimumab.
Incorrect. In the BLISS-LN trial for lupus nephritis, corticosteroids were tapered to less than 10 mg/day by week 24 to minimize steroid exposure while maintaining efficacy in combination with belimumab and standard immunosuppressive therapy.

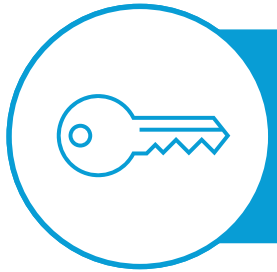
c. Cyclosporine.
Incorrect. KDIGO recommends either cyclosporine or tacrolimus for at least 6 months in adults with steroid-resistant FSGS, rather than continuing glucocorticoid monotherapy or providing no immunosuppression.

**d. Losartan.**
**Correct.** RAS inhibition is a cornerstone of management in the setting of proteinuric renal disease but would not be considered a steroid sparing agent in the setting of glomerular disease.

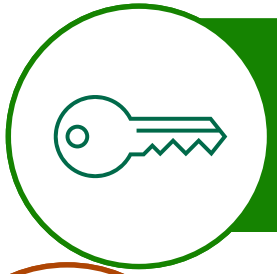
# Key Takeaways



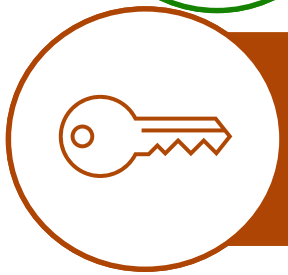
Use patient comorbidities, lifestyle, and reproductive plans in shared decision-making for treatment



Use therapeutic agents strategically to minimize drug toxicity



Use a multidisciplinary team including pharmacists, nurses, and the PCP to help with management



Be aware of new drugs and changing guidelines in the management of glomerular disease

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# Advancing Kidney Health

## Through Optimal Medication Management

**Thank you!**