Monoclonal Antibodies: A Pharmacological Review
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Disclosure

• No conflicts of interest to disclose
Objectives

- Define biological agents
- Classify monoclonal antibodies (mAb)
- Describe various mechanisms of action (MOA) for monoclonal antibodies
- Review adverse effects of mAb’s
- Identify major therapeutic uses of mAb’s
- Describe therapeutically important mAb’s
- Discuss future directions of mAb development
Biological Agents

- Blood Factors
- Thrombolytics
- Hormones
- Hematopoietic Growth Factors
- Interferons
- Vaccines
- Interleukins
- Monoclonal Antibodies (mAb’s)

Antibody Structure

Antibody (immunoglobulin secreted by B cells)

Antigen (foreign substance that stimulates antibody production)

Epitope (antibody binding site)

Paratope (antigen-binding site)

Fv, variable region of light chain

VH, hypervariable regions of heavy chain

VL, hypervariable regions of light chain

Fv, variable region of heavy chain

CL, hinge

Fab

Fc

CH1

CH2

CH3

All mAb’s function to bind specific targets and expedite removal via immune system

Specific mechanisms

- Antibody dependant cytotoxicity
- Complement mediated cytotoxicity
- Direct cytotoxicity
- Antibody-drug conjugate

MOA- Antibody Dependant Cytotoxicity
MOA - Complement Mediated Cytotoxicity
MOA - Direct Cytotoxicity

Inhibit receptor dimerization

Block ligand

Induce apoptotic signalling

MOA - Antibody Drug Conjugate

1. ADC in plasma

2. ADC binds to antigen protein

3. ADC-antigen protein complex is internalized

4. ADC-antigen protein complex is degraded releasing cytotoxin

5. Cytotoxin binds to target

6. Causes apoptosis (Cell death)

DNA strand breakage

Microtubule disruption

Lysosome

Antigen
## Monoclonal Antibody Nomenclature

<table>
<thead>
<tr>
<th>Prefix</th>
<th>Target Substem</th>
<th>Suffix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique to drug</td>
<td></td>
<td>umab (human)</td>
</tr>
<tr>
<td>Bacterial = bac</td>
<td>Viral = vir</td>
<td>omab (mouse)</td>
</tr>
<tr>
<td>Immune = lim</td>
<td>Cardiovascular = cir</td>
<td>ximab (chimeric)</td>
</tr>
<tr>
<td>Bone = os; so</td>
<td>Interleukin = ki</td>
<td>zumab (humanized)</td>
</tr>
<tr>
<td>Colonic tumor = col</td>
<td>Misc. tumor = tum</td>
<td></td>
</tr>
</tbody>
</table>

Example

**Denosumab**

- **Prefix (unique):** Den
- **Suffix:** Human monoclonal antibody
- **Target substem:** Bone
Major Uses of Monoclonal Antibodies

Oncology

Inflammatory conditions

Misc.
Percutaneous coronary intervention, osteoporosis, drug binding

Drug Targets

**Oncology**
- Epidermal growth factor receptor (EGFR)
- Vascular Endothelial Growth Factor (VEGF)
- Human epidermal growth factor-2 receptor (HER-2)
- CD30
- CD20

**Inflammatory**
- Tumor necrosis factor α (TNFα)
- Interleukin-2 (IL-2)
- Immune globulin G (IgG)
- Human B lymphocyte stimulator protein (BLyS)

**Miscellaneous**
- Receptor activator of nuclear factor kappa-B ligand (RANKL)
- GP IIb/IIIa
- Drug binding targets

Hypersensitivity Reactions of mAb’s

- **Murine (0% human)**
- **Chimeric (65% human)**
- **Humanized (> 90% human)**
- **Fully Human (100% human)**

Generic suffix:
- -ornab
- -ximab
- -zumab
- -umab

High Potential for immunogenicity

## Infection Risk of mAb’s

<table>
<thead>
<tr>
<th>Anti-inflammatory MAB</th>
<th>Anti-Cancer MAB</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgG</td>
<td>CD30</td>
</tr>
<tr>
<td>TNF α</td>
<td>EGFR</td>
</tr>
<tr>
<td>Interleukin 2</td>
<td>HER2</td>
</tr>
<tr>
<td>Human B lymphocyte stimulator protein (BLyS)</td>
<td>VEGF</td>
</tr>
</tbody>
</table>

Degree of infection may vary from mild local infections to severe life threatening sepsis with both pathogenic and opportunistic organisms.

**Malignancy Risk of mAb’s**

- **TNF-α inhibitors**

<table>
<thead>
<tr>
<th>Increased Cancer Risk</th>
<th>Non-significant cancer risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Data stems from initial trials</td>
<td>a) No long term difference in incidence of cancer (3.7 years)</td>
</tr>
<tr>
<td>b) Low number of cancer rates overall</td>
<td>b) Increased risk of lymphoma</td>
</tr>
<tr>
<td>c) Most patients were treated with combination therapies</td>
<td>2. Meta-analysis in rheumatoid arthritis patients, N=22,130</td>
</tr>
<tr>
<td>d) Rate of cancer was comparable to general population</td>
<td>a) Decreased risk of all cancers</td>
</tr>
<tr>
<td></td>
<td>b) Increased risk of lymphoma</td>
</tr>
<tr>
<td></td>
<td>3. Meta-analysis of all TNF-α inhibitors, N=15,418</td>
</tr>
<tr>
<td></td>
<td>a) No increased overall cancer risk</td>
</tr>
<tr>
<td></td>
<td>b) Increased risk of non-melanoma skin cancer</td>
</tr>
</tbody>
</table>

JAMA. 2014 Jun 18;311(23):2406-13
Arthritis Res Ther. 2014 Sep 30;16(5):449
<table>
<thead>
<tr>
<th>Name</th>
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<th>Year</th>
</tr>
</thead>
</table>
Antineoplastic Monoclonal Antibodies
# Cetuximab (Erbitux®)

<table>
<thead>
<tr>
<th>Indication</th>
<th>KRAS wild type and EGFR positive metastatic colorectal cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MOA</strong></td>
<td>Murine-human chimeric monoclonal antibody directed against EGFR</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>Loading dose of 400 mg/m² IVPB over 2 hr followed by 250 mg/m² over 1 hour once weekly</td>
</tr>
<tr>
<td><strong>ADE</strong></td>
<td>Infusion reactions, rash, neuropathy, depression, neutropenia, electrolyte abnormalities</td>
</tr>
<tr>
<td><strong>Warnings/CI</strong></td>
<td>Fatal infusion reactions, concomitant use with cisplatin and radiation, dermatological reactions, and electrolyte abnormalities</td>
</tr>
<tr>
<td><strong>Monitoring Parameters</strong></td>
<td>Infusion reactions (pre-medication); electrolytes (Mg, K, Ca), presence of rash</td>
</tr>
</tbody>
</table>
Cetuximab - Place in Therapy

- First line therapy for KRAS expressing, EGFR positive metastatic colorectal cancer
  - In combination with:
    - FOLFIRI (irinotecan, 5-fluorouracil, and leucovorin)
    - FOLFOX (oxaliplatin, 5-fluorouracil, and leucovorin)

- After failure of oxaliplatin & irinotecan based regimens
  - Used as monotherapy
  - Improved survival from 4.6 to 6.1 months

- Orphan drug designation for squamous cell head & neck cancer

Cetuximab. In: Lexi-Drugs Online
Special Considerations

• Storage
  ▫ Refrigeration at 2°C to 8°C, protect from light, do not shake vigorously

• Administration
  ▫ Pretreatments: diphenhydramine, acetaminophen
  ▫ Stability: 8-12 hours

• Pricing
  ▫ 100/50ml average wholesale price (AWP): $636.18

• Caveats
  ▫ Severity of dermatological reactions correlate with efficacy, future dosing and use of oral/topical/IV steroids and antibiotics for treatment
Grade 1 EGFR Rash

Treatment:

1. Topical clindamycin 2% BID
2. Hydrocortisone 1% in lotion base BID
Grade 2 EGFR Rash

Treatment:

1. Topical clindamycin 2% BID
2. Hydrocortisone 1% in lotion base BID
3. Doxycycline 100 mg BID minimum of 4 weeks
Grade 3 EGFR Rash

Treatment:

1. Withhold treatment until rash improves < grade 2
2. Topical clindamycin 2% BID
3. Hydrocortisone 1% in lotion base BID
4. Doxycycline 100 mg BID minimum of 4 weeks
Grade 4 EGFR Rash

Treatment:
1. Withhold treatment until rash improves < grade 2
2. Topical clindamycin 2% BID
3. Hydrocortisone 1% in lotion base BID or triamcinolone 0.05% cream
4. IV antibiotics and steroids indicated
## Bevacizumab (Avastin®)

<table>
<thead>
<tr>
<th>Indication</th>
<th>Glioblastoma, metastatic breast cancer, metastatic colon cancer, metastatic renal cell carcinoma, non squamous non small cell lung cancer, ovarian cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOA</td>
<td>Recombinant humanized monoclonal antibody directed against vascular endothelial growth factor (VEGF)</td>
</tr>
<tr>
<td>Dose</td>
<td>5-15 mg /kg depending on indication IVPB over 60-90 minutes</td>
</tr>
<tr>
<td>ADE</td>
<td>Hypertension, thromboembolism, rash, proteinuria, hemorrhage</td>
</tr>
<tr>
<td>Warnings/CI</td>
<td>BBW: GI perforation, impaired wound healing, and hemorrhage</td>
</tr>
<tr>
<td></td>
<td>Venous and arterial thrombosis, infusion reactions, fistulae formation, proteinuria, hypertension</td>
</tr>
<tr>
<td>Monitoring Parameter</td>
<td>Blood pressure, urine analysis, infusion reactions, hand-foot syndrome</td>
</tr>
</tbody>
</table>
Bevacizumab - Place In Therapy

• Metastatic colon cancer
  ▫ First or second line treatment
  ▫ In combination with FOLFOXIRI or FOLFIRI

• Metastatic breast cancer
  ▫ In combination with paclitaxel

• NSCLC unresectable, locally advanced, recurrent, or metastatic
  ▫ In combination with carboplatin and paclitaxel
Special Considerations

• **Storage**
  ▫ Refrigeration at 2°C to 8°C, protect from light, do not shake vigorously

• **Administration**
  ▫ Pretreatments: not studied
  ▫ Stability: 8 hours

• **Pricing**
  ▫ 100mg/4ml AWP: $832.74

• **Caveats**
  ▫ Must be held at least 28 days prior to and after surgery
### Trastuzumab (Herceptin®)

<table>
<thead>
<tr>
<th>Indication</th>
<th>HER-2 positive breast cancer, adjuvant or metastatic Metastatic gastric cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MOA</strong></td>
<td>Humanized monoclonal antibody that binds to HER-2 receptors and helps trigger antibody-dependent cell-mediated cytotoxicity (ADCC)</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>2-8 mg/kg via IVPB over 30-90 minutes for 52 weeks</td>
</tr>
<tr>
<td><strong>ADE</strong></td>
<td>Heart failure, rash, infection</td>
</tr>
<tr>
<td><strong>Warnings/CI</strong></td>
<td>Cardiomyopathy, infusion reactions, pulmonary toxicity, fetal harm</td>
</tr>
<tr>
<td><strong>Monitoring Parameters</strong></td>
<td>HER-2 over-expression baseline confirmation, cardiac indices, pulmonary indices, hypersensitivity reactions</td>
</tr>
</tbody>
</table>
Trastuzumab - Place in Therapy

• Adjuvant for breast cancer
  ▫ Doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
  ▫ Docetaxel and carboplatin
  ▫ Single agent following anthracycline-based therapy

• Metastatic breast cancer
  ▫ Monotherapy
  ▫ In combination with paclitaxel

• Metastatic gastric cancer
  ▫ In combination with either cisplatin and capecitabine
Special Considerations

- **Storage**
  - Refrigeration at 2°C to 8°C, protect from light, do not shake vigorously

- **Administration**
  - Premedication: antihistamines, corticosteroids
  - Stability: 28 days under refrigeration

- **Pricing**
  - 440 mg AWP: $4594.10

- **Caveats**
  - Avoid anthracycline therapy for at least 7 months after trastuzumab discontinuation.
  - Should not be used for > 1 year for adjuvant therapy
Antibodies
## Adalimumab (Humira®)

<table>
<thead>
<tr>
<th>Indications</th>
<th>Ankylosing spondylitis, Crohn's, hidradenitis suppurativa, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOA</td>
<td>Tumor necrosis – alpha inhibitor (TNFα)</td>
</tr>
<tr>
<td>Dose</td>
<td>Dosing strength and frequency depends on indication</td>
</tr>
<tr>
<td>ADE</td>
<td>Headache, rash, injection site reaction, Upper respiratory tract infection</td>
</tr>
<tr>
<td>Warnings/CI</td>
<td>Anaphylaxis, autoimmune disorder, demyelinating disease, heart failure, hepatitis B, pancytopenia, Black Boxed warnings: serious infections, malignancy, tuberculosis</td>
</tr>
<tr>
<td>Monitoring Parameters</td>
<td>Monitor for s/s of improvement, vital signs during infusion, signs of aforementioned infections and malignancy</td>
</tr>
</tbody>
</table>
TNF Antagonist - Place in Therapy

• **Moderate-severe or chronic disabling cases**
• **Crohn's disease**
  ▫ No clear cut 1st line option: adalimumab, infliximab, certolizumab
• **Hidradenitis suppurativa, ulcerative colitis**
  ▫ Typically the second line TNF antagonist after infliximab
• **Plaque psoriasis, psoriatic arthritis**
  ▫ Various TNF antagonists indicated in moderate-severe cases
Treatment Recommendations for Early Rheumatoid Arthritis

Singh JA. Et al Arthritis Rheumatol. 2015;
Adalimumab Special Considerations

- **Storage**
  - Refrigerate at 2°C to 8°C

- **Administration:**
  - SubQ injection in the thigh or lower abdomen
  - Do not administer to skin which is red, tender, bruised, or hard
  - Pretreatments: Acetaminophen and diphenhydramine

- **Pricing**
  - 40mg/0.8ml AWP: $2073.04

- **Caveats**
  - Avoid concurrent TNF-blocking agents (abatacept, anakinra)
# Omalizumab (Xolair®)

<table>
<thead>
<tr>
<th>Indication</th>
<th>Moderate to severe asthma</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MOA</strong></td>
<td>Humanized IgE mAb that inhibits binding of IgE to high affinity IgE receptor</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>Dose based on baseline IgE levels and body weight Administered every 2-4 weeks</td>
</tr>
<tr>
<td><strong>ADE</strong></td>
<td>Thromboembolism, rash, local injection reactions, arthralgias</td>
</tr>
<tr>
<td><strong>Warnings/CI</strong></td>
<td>Anaphylactic reactions may occur at any time after the first dose to more than a year after initiation</td>
</tr>
<tr>
<td><strong>Monitoring Parameters</strong></td>
<td>Baseline IgE levels, eosinophilia, stool assessment for parasitic helminthes</td>
</tr>
</tbody>
</table>
Omalizumab - Place in Therapy

Persistent asthma: Daily medication
Consult with asthma specialist if step 4 care or higher is required
Consider consultation at step 3

Step 1
Preferred: SABA PRN

Step 2
Preferred: Low-dose ICS
Alternative: Cromolyn, LTRA, nedocromil, or theophylline

Step 3
Preferred: Medium-dose ICS + LABA
Alternative: Medium-dose ICS + LTRA, theophylline, or zileuton

Step 4
Preferred: High-dose ICS + LABA
AND
Consider omalizumab for patients who have allergies

Step 5
Preferred: High-dose ICS + LABA + oral corticosteroid
AND
Consider omalizumab for patients who have allergies

Step 6
Preferred: High-dose ICS + LABA + oral corticosteroid
AND
Consider omalizumab for patients who have allergies

Intermittent asthma
Special Considerations

• Storage
  ▫ Refrigeration at 2°C to 8°C, protect from light, do not shake vigorously

• Administration
  ▫ Stability: 4-8 hours
  ▫ Subcutaneous injection

• Pricing
  ▫ 150 mg AWP: $1090.79

• Caveats
  ▫ Doses $\geq$ 150 mcg must be administered at different sites
  ▫ IgE levels should only be used to guide dosing if therapy is interrupted for $\geq$ 1 year
# Belimumab (Benlysta®)

<table>
<thead>
<tr>
<th>Indications</th>
<th>Systemic lupus erythematosus (SLE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOA</td>
<td>IgG1-lambda mAb that prevents the survival of B lymphocytes</td>
</tr>
<tr>
<td>Dose</td>
<td>Initial: 10 mg/kg every 2 weeks for 3 doses; Maintenance: 10 mg/kg every 4 weeks</td>
</tr>
<tr>
<td>ADE</td>
<td>NVD and injection site reaction</td>
</tr>
<tr>
<td>Warnings/ CI</td>
<td>Hypersensitivity, infections, malignancy, mortality, Progressive multifocal leukoencephalopathy, Immunizations</td>
</tr>
<tr>
<td>Monitoring Parameters</td>
<td>Hypersensitivity, infusion reactions, depression, mood changes, suicidal ideations</td>
</tr>
</tbody>
</table>
Place in Therapy

• First Line treatment
  ▫ Hydroxychloroquine or chloroquine
    • Consider NSAID’s and/or low dose glucocorticoids

• Moderate severity
  ▫ Azathioprine, methotrexate, or mycophenolate mofetil

• Continued treatment failure in autoantibody SLE
  ▫ Belimumab
    • Minimal evidence for severe active lupus nephritis or severe active CNS lupus
Special Considerations

• **Storage**
  - Refrigerate at 2°C and 8°C

• **Administration**
  - Administer IVPB only, over 1 hour through a dedicated IV line

• **Pricing**
  - 400 mg AWP: $1909.72

• **Caveats**
  - Black/African-American patients sometimes have lower response rate
  - Live vaccines should not be given within 30 days before or concurrently
Miscellaneous Monoclonal Antibodies
## Denosumab (Prolia®, Xgeva®)

| Indications | Xgeva®: hypercalcemia of malignancy, prevention of skeletal-related events in bone metastases, giant cell bone tumor  
Prolia®: Androgen deprivation-induced bone loss in prostate CA, aromatase inhibitor-induced bone loss in breast CA, osteoporosis |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>MOA</td>
<td>mAb with affinity for nuclear factor-kappa ligand (RANKL)</td>
</tr>
</tbody>
</table>
| Dose        | Xgeva®: SubQ: 120 mg every 4 weeks  
Prolia®: SubQ: 60 mg every 6 months                                                                           |
| ADE         | Hypertension, fatigue, headache, hypophosphatemia, NVD                                                           |
| Warnings/CI | Dermatologic, hypocalcemia, bone fractures, infections, osteonecrosis of the jaw, musculoskeletal pain pregnancy (Prolia® only), caution in dialysis patients |
| Monitoring Parameter | Serum creatinine, electrolytes (Ca, phos, Mg), hypersensitivity, thyroid function test, bone mineral density, dental exam |
Denosumab - Place in Therapy

Management of Hypercalcemia of Malignancy

Severe Hypercalcemia: Ca >14 mg/dL

Volume Expansion

Salmon calcitonin 4 units/kg

No

Is CrCl > 30 mL/min?

Denosumab

Yes

Zoledronic Acid or Pamidronate

Consider denosumab if bisphosphonate fails
Management of Bone Disease Associated with Breast Cancer Treatment

- **Bone disease present**
  - Add denosumab, zoledronic acid, or pamidronate
  - ER and/or PR positive; HER2 negative
    - ER and/or PR positive; HER2 positive
    - ER and PR negative, or ER and/or PR positive and endocrine refractory; HER2 negative
    - ER/PR negative or ER and/or PR positive and endocrine refractory; HER2 positive

- **Systemic disease or de novo stage IV**
  - Bone disease not present

**Osteoporosis**
- Rarely 1st line therapy
- Not intended for premenopausal women or children

Special Considerations

- **Storage:**
  - Refrigerate at 2°C - 8°C, protect from heat and light, do not shake

- **Administration**
  - SubQ injection only
  - Solution may contain traces of translucent to white protein particles
  - Premedication: Acetaminophen

- **Pricing**
  - Xgeva®- 120 mg AWP: $2262
  - Prolia®- 60 mg AWP: $1141.92

- **Caveats**
  - Must correct hypocalcemia before starting therapy (Prolia®)
  - Increased risk of mortality in multiple myeloma
# Idarucizumab (Praxbind®)

<table>
<thead>
<tr>
<th>Indication</th>
<th>Reversal of dabigatran</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOA</td>
<td>Humanized mAb fragment (FAb) that binds specifically to dabigatran and its acylglucuronide metabolites to neutralize the anticoagulant effect</td>
</tr>
<tr>
<td>Dose</td>
<td>5 g (administered as 2.5 g doses no more than 15 minutes apart)</td>
</tr>
<tr>
<td>ADE</td>
<td>Delirium, headache, constipation, hypokalemia</td>
</tr>
<tr>
<td>Warnings/CI</td>
<td>Elevated coagulation parameters with bleeding, avoid in those with fructose intolerance, hypersensitivity reactions</td>
</tr>
<tr>
<td>Monitoring Parameters</td>
<td>Reversal of anticoagulation for efficacy, no specific monitoring determined yet</td>
</tr>
</tbody>
</table>

Place in Therapy

- Reversal of the anticoagulant effects of dabigatran
  - Emergency surgery/urgent procedures or in life-threatening
  - Uncontrolled bleeding

Special Considerations

- **Storage**
  - Refrigerate at 2°C to 8°C, protect from light, do not shake

- **Administration**
  - First flush line with NS
  - Two 2.5 mg IVPB doses 10-15 minutes apart
  - Administer through its own line

- **Pricing**
  - 2.5 g/50 mL AWP: $2100

- **Caveats:**
  - Only reversal agent for a novel oral anticoagulant
  - Efficacy of a repeat dose for clinically relevant bleed unknown
Future of mAb’s
• **Biosimilars**

  - **Biologics Price Competition and Innovation Act**

  - **Biosimilar**
    - Highly similar to the reference product, but not identical
    - No clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product

  - **Examples**
    - **Infliximab (Remsima®/Inflectra®)**
    - **Filgrastim-sndz (Zarxio®)**
Potential Issues with Biosimilars

- **Biosimilarity**
  - Cannot be identical to the reference drug
  - MOA must target similar receptors or functions

- **Extrapolation**
  - Must be done by individual indication and dose
  - Clinically relevant MOA may differ by indication
  - Physicochemical properties of the reference drug may change over time

Potential Issues with Biosimilars

• “Switchability”
  ▫ Discretion of the prescriber
• Immunogenicity
  ▫ Few issues with current biosimilars
• Pharmacovigilance
  ▫ Crucial due to poor drug characterization in trials
• Nomenclature
  ▫ No internationally accepted nomenclature
  ▫ Brand AND generic as identifier
Future Research

• Infectious Diseases
  ▫ Neutralization of Ebola virus
  ▫ Interference of influenza virus replication
  ▫ Activity against multi-drug resistant bacteria

• Improvements in manufacturing and product quality
Conclusions

• Complex antibody structure presents limitless opportunities for drug targets
• Two main therapeutic areas of use, although new uses are being rapidly developed
• Risk of infection with mAb’s is related to antibody target
• Risk of malignancy with TNFα inhibitors is controversial
• Pharmacovigilance is imperative with the emergence of biosimilars
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