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EXPERT OPINION

Health Technology Assessment: Evaluation of Monoclonal Antibodies for the Treatment of Neuromyelitis Optica Spectrum Disorders

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Objective: To systematically evaluate the clinical value of monoclonal antibodies for neuromyelitis optica spectrum disorders (NMOSD), a multidimensional assessment of three monoclonal antibody therapies (eculizumab, inebilizumab, and satralizumab) was conducted using the updated drug evaluation framework from the Rapid Guide for Drug Evaluation and Selection in Chinese Medical Institutions (2nd Edition). This study aims to provide evidence-based guidance for optimizing monoclonal antibody selection in clinical practice.

Methods: A quantitative scoring system was employed across five distinct domains: pharmacological properties (28 points), efficacy (27 points), safety (25 points), economics (10 points), and other attributes (10 points).

Results: The comprehensive evaluation scores, with a maximum of 100 points, were as follows: eculizumab (70.43), satralizumab (69.33), and inebilizumab (68).

Conclusion: Eculizumab is strongly endorsed as the first-line therapeutic option due to its optimal benefit-risk profile. Satralizumab and inebilizumab may be considered as conditional alternatives, contingent upon institutional resources and individual patient factors. This tiered recommendation framework facilitates adaptive formulary management that aligns with the evolving therapeutic landscape and socioeconomic conditions, thereby providing a replicable model for healthcare systems worldwide.

Keywords: monoclonal antibodies, satralizumab, inebilizumab, eculizumab, NMOSD, health technology assessment

Introduction

Neuromyelitis optica spectrum disorders (NMOSD) represent a rare autoimmune demyelinating condition, with an incidence ranging from 0.7 to 10.0 per 100,000 individuals,[1,2] and it predominantly affects women, posing significant risks of disability due to recurrent neuroinflammatory episodes.[3,4] Over the past century, substantial advancements have been made in the understanding of NMOSD. Historically, treatment has relied on off-label immunosuppressants, such as mycophenolate mofetil and azathioprine,[5] however, treatment strategies have undergone significant transformation following the identification of aquaporin-4 immunoglobulin G (AQP4-IgG) as a key pathogenic factor.[6] The introduction of monoclonal antibodies, including eculizumab (a complement C5 inhibitor), inebilizumab (a CD19+ B-cell depleter), and satralizumab (an IL-6 receptor antagonist), has facilitated the emergence of targeted immunotherapy, demonstrating promising efficacy.[7] The approval of these novel agents marks a significant advancement in the therapeutic landscape for NMOSD. Currently, the National Medical Products Administration (NMPA) has sanctioned the use of eculizumab, inebilizumab, and satralizumab for NMOSD treatment. Nonetheless, the high costs associated with these therapies and their unique pharmacodynamic characteristics necessitate the implementation of evidence-based selection frameworks. For NMOSD patients who are AQP4-IgG positive, a critical factor in selecting between eculizumab, inebilizumab, or

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satralizumab is the patient's response to prior treatments. If a monoclonal antibody has been administered and has reached its therapeutic window but the treatment fails, another monoclonal antibody should be considered. When changing medications due to treatment failure, it is advisable to avoid drugs with similar mechanisms of action, as their efficacy would likely be comparable.[5,8] Consequently, these three monoclonal antibodies, with distinct mechanisms of action, provide additional options for patients.

Rapid health technology assessment (rHTA) is an evidence evaluation method that quickly assesses the pharmaceutical properties, efficacy, safety, and economics of drugs through simplified health technology assessment methods and processes, thereby providing evidence support for decision-makers. rHTA is a streamlined evidence synthesis approach designed to support time-sensitive decision-making while maintaining methodological rigor.[9] Compared to full Health Technology Assessment (HTA), rHTA focuses on evaluating specific issues rather than conducting exhaustive analysis, aiming to obtain the best evidence within a short time frame.[10] Additionally, rHTA focuses on systematic yet practical literature reviews with clear temporal filters, rapidly integrating evidence using predefined scoring algorithms to meet policymakers' needs. Given that monoclonal antibodies represent emerging therapies requiring urgent clinical guidance, rHTA is highly applicable for the therapeutic evaluation of NMOSD. This study presents an innovative application of rHTA, adapting the Rapid Guide for Drug Evaluation and Selection in Chinese Medical Institutions *(2nd Edition)* (hereinafter referred to as "The Second Edition") to systematically compare biologic therapies for NMOSD. "The Second Edition" aligns with the core principles of European Network for Health Technology Assessment (EUnetHTA)'s HTA Core Model® while incorporating local formulary considerations. The evaluation dimensions and weights were determined by the guideline guidance group and the expert group through the Delphi method. Moreover, compared to the first edition, the expert panel revised and refined the evaluation indicators for pharmaceutical assessment and selection in healthcare institutions, allowing the quantified scores to better reflect the priority of drugs within these institutions and align more closely with national policy requirements, while also offering more detailed, clear, and operational scoring criteria.[11] Unlike Grading of Recommendations Assessment, Development and Evaluation (GRADE), which focused on evidence quality, our multidimensional scoring system integrates five distinct dimensions: pharmacological properties, efficacy, safety, economics, and other attributes. This methodology balances scientific validity with healthcare systems' need for timely recommendations, consistent with WHO's "Faster Access to Important New Health Technologies" initiatives. Previous applications of rapid comprehensive evaluations of other pharmaceuticals have been conducted based on this framework.[12,13] This investigation is the first to conduct a thorough evaluation of three monoclonal antibody therapies for NMOSD patients utilizing this guide, thereby providing a scientific foundation for drug selection and decision-making within medical institutions and serving as a reference for healthcare decisions in other regions.

Materials and Methods

Evaluation Framework

This research utilized the "The Second Edition", which integrates the Mini-Health Technology Assessment (Mini-HTA) with the Structured Operational Judgment Approach (SOJA) framework. The evaluation criteria and corresponding weighting coefficients were developed through a modified Delphi consensus process. A validated multi-criteria decision analysis (MCDA) tool was employed to evaluate monoclonal antibodies across five domains: pharmacological properties, efficacy, safety, economic considerations, and other attributes.

Evaluation of Drugs

In recent years, there has been a continuous emergence of novel monoclonal antibody therapies targeting new therapeutic pathways. Monoclonal antibodies indicated for aquaporin-4 (AQP4) antibody-positive NMOSD are endorsed by several clinical guidelines,[1,5,14] with five primary agents identified: Rituximab, a chimeric monoclonal antibody targeting CD20; Eculizumab, a humanized IgG2/4 monoclonal antibody functioning as a terminal complement protein C5 inhibitor; Satralizumab, a humanized IgG2 subtype recombinant monoclonal antibody targeting the interleukin-6 receptor (IL-6R); Inebilizumab, a humanized IgG subtype monoclonal antibody targeting CD19; Tocilizumab, another IL-6R targeted monoclonal antibody.

Table 1 Drugs Included in the Evaluation

Drug Name/ Brand Name	Target	Dosage Form (Route of Administration)	Specification	Approved Regions (Year)	Manufacturer
Satralizumab / Enspryng	IL-6R Inhibitor	Injection (Subcutaneous)	120 mg (1 mL)/vial	China (2021), United States (2020), Europe (2021), Japan (2020)	Utsunomiya Plant of Chugai Pharma Manufacturing Co., Ltd.
Inebilizumab / Uplizna	CD19 Monoclonal Antibody	Injection (Intravenous Infusion)	100 mg (10 mL)/vial	China (2022), United States (2020), Europe (2022), Japan (2021)	AstraZeneca Nijmegen B.V.
Eculizumab / Soliris	C5 Complement Protein Inhibitor	Injection (Intravenous Infusion)	300 mg/30 mL	China (2022), United States (2019), Europe (2019), Japan (2019)	Alexion Pharma International Operations Limited Alexion Athlone Manufacturing Facility (AAMF)

This study specifically focused on monoclonal antibodies that have received approval from the NMPA for NMOSD indications in China, namely eculizumab injection, inebilizumab injection, and satralizumab injection. The indications for these three monoclonal antibodies in the treatment of NMOSD have also been approved by the Food and Drug Administration (FDA) and European Medicines Agency (EMA). The drugs included in the final evaluation are detailed in Table 1.

Quantitative Evaluation Criteria

The rapid comprehensive evaluation of monoclonal antibodies was based on "The Second Edition". This assessment encompassed various dimensions, elements, weights, and implications associated with drug evaluation and selection, which included pharmacological properties (28 points), efficacy (27 points), safety (25 points), economics (10 points), and other attributes (10 points).

Retrieval and Evaluation of Relevant Evidence

The retrieval process involved the examination of drug package inserts and official government websites, such as the FDA. A systematic search was conducted independently by two pharmacists across English-language databases, including PubMed, Embase, and the Cochrane Library, Web of Science, as well as the Chinese Biomedical Literature Database (CBM), WanFang database and the China National Knowledge Infrastructure (CNKI). Two pharmacists independently assessed the retrieved materials, and in instances where their evaluations diverged significantly (by more than three points), a third expert in the relevant field was consulted to facilitate discussion and reach a consensus on the final evaluation. The results of this evaluation were subsequently adapted for application in drug selection and the formulation of clinical medication regimens within medical institutions.

Search strategy for PubMed: (("Neuromyelitis Optica"[Mesh]) OR ((((((((((((((Neuromyelitis Optica Spectrum Disorder) OR (NMO Spectrum Disorder)) OR (Neuromyelitis Optica Spectrum Disorder)) OR (Devic's Disease)) OR (Devics Disease)) OR (Disease, Devic's)) OR (Devic Disease)) OR (Disease, Devic)) OR (Devic Syndrome)) OR (Devic's Syndrome)) OR (Devics Syndrome)) OR (Devic's Neuromyelitis Optica)) OR (Devics Neuromyelitis Optica)) OR (Neuromyelitis Optica, Devic's)) OR (Devic Neuromyelitis Optica)) OR (Neuromyelitis Optica, Devic))) AND ((((((((((eculizumab) OR (Soliris)) OR (5G1.1)) OR (H5G1-1)) OR (H5G11)) OR (H5G1.1)) OR (H5G1.1VHC +H5G1.1VLC)) OR (Alexion)) OR (Elizaria)) OR ((Satralizumab) OR (enspryng))) OR (((Inebilizumab) OR (MEDI-551)) OR (MEDI551))).

Inclusion criteria were: (a) Study type: RCT (randomized controlled trial) or meta analysis; (b) Language restriction: Chinese or English literature; (c) Participants: patients who were diagnosed with NMOSD according to the 2015

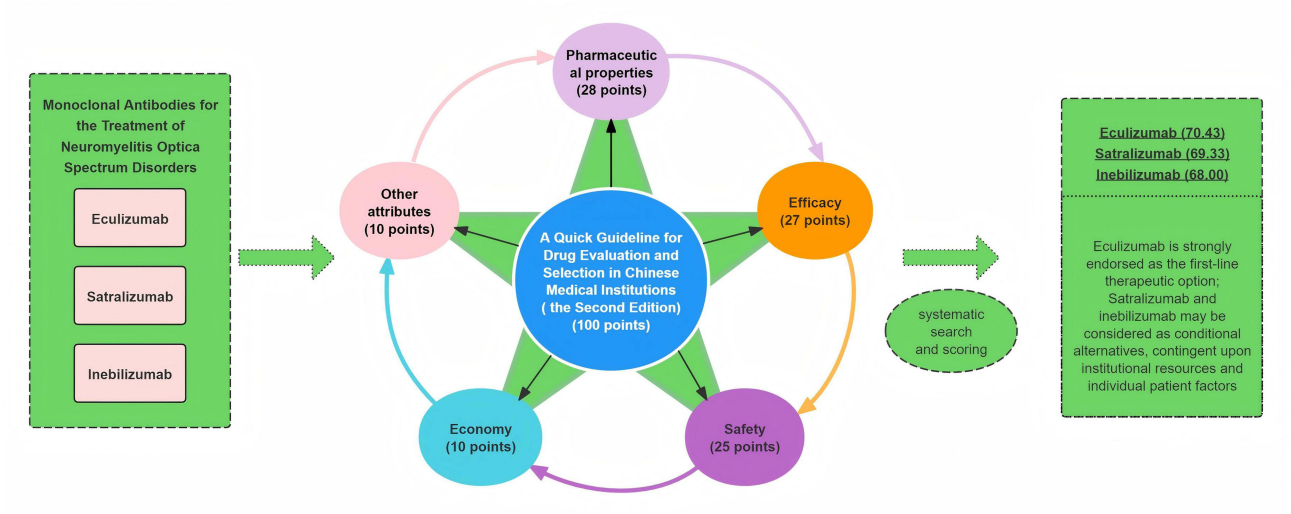

Figure 1 Flowchart for rapid comprehensive evaluation of three monoclonal antibodies used in the treatment of NMOSD.

International Panel for Neuromyelitis Optica Diagnosis criteria or 2006 NMO diagnosis criteria; (d) Intervention: three monoclonal antibody therapies (eculizumab, inebilizumab, and satralizumab); (e) Efficacy Outcomes: relapse risk, ARR (annualized relapse rate) ratio and EDSS (Expanded Disability Status Scale) score change; (f) Safety Outcomes: adverse events, serious adverse events and death. Exclusion criteria were: (a) Study types: case reports, reviews, retrospective studies and cohort studies; (b) Duplicate literature and conference abstracts; (c) Non-Chinese/English literature.

Figure 1 shows a flowchart for rapid comprehensive evaluation of three monoclonal antibodies used in the treatment of NMOSD.

Results

Pharmacological Properties

A comparative evaluation of the pharmacological characteristics was performed across five distinct domains: pharmacological action, in vivo processes, pharmacy and method of use, storage conditions, and drug shelf life.

Pharmacological Action

All three monoclonal antibodies demonstrate evident clinical efficacy; NMOSD is a central nervous system autoimmune disease mediated by AQP4-IgG. Current immunotherapy target drugs are primarily developed based on this pathogenic mechanism, including complement C5 inhibitor eculizumab, anti-CD19 monoclonal antibody inebilizumab, and interleukin-6 receptor inhibitor satralizumab. The three investigated monoclonal antibodies exhibit distinct yet complementary mechanisms targeting the NMOSD pathogenesis cascade. Eculizumab is presumed to involve inhibition of AQP4-antibody-induced terminal complement C5b-9 deposition; Satralizumab is presumed to involve inhibition of IL-6-mediated signaling through binding to soluble and membrane-bound IL-6 receptors; Inebilizumab is presumed to involve binding to CD19, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, inebilizumab-cdon results in antibody-dependent cellular cytotoxicity. Given that their targets diverge from those of conventional immunosuppressants, each antibody was assigned a score of 5 points.

In vivo Processes

The in vivo processes associated with all three monoclonal antibodies are well-defined, with complete pharmacokinetic parameters, resulting in a score of 5 points for each.

Pharmacy and Method of Use

The main components and excipients of the three monoclonal antibodies are clearly identified, with specifications and packaging that are appropriate for clinical application and dose adjustment, leading to a score of 2 points for each.

Satralizumab is administered via subcutaneous injection, which earned it 1.5 points, while the other two antibodies necessitate intravenous administration, each receiving a score of 1 point. All three monoclonal antibodies require dose adjustments during treatment (including initial and maintenance doses). Eculizumab, Initiation phase: 900 mg intravenous infusion weekly for the first 4 weeks; Maintenance phase: 1200 mg intravenous infusion at week 5, followed by 1200 mg every 14±2 days. The drug follows a one-compartment model with an average elimination half-life of 11.3±3.4 days. Satralizumab, Loading dose: 120 mg subcutaneous injection at weeks 0, 2, and 4; Maintenance dose: 120 mg subcutaneous injection every 4 weeks. The terminal half-life is approximately 30 days (22–37 days). Inebilizumab, Initial dose: 300 mg intravenous infusion on day 1 and day 15; Subsequent doses: 300 mg intravenous infusion every 6 months. The elimination pharmacokinetics in NMOSD patients exhibit biphasic characteristics with an average terminal half-life of 18 days. resulting in a score of 1.5 points for each. Despite variations in dosing regimens, the average dosing frequency for all three is less than once per day, which also earned them a score of 2 points. Furthermore, administration of all three antibodies must be conducted by qualified medical personnel, resulting in an additional score of 1 point for each.

Storage Conditions

All three monoclonal antibodies necessitate refrigeration for storage, which earned them a score of 1 point each.

Drug Shelf Life

Inebilizumab and satralizumab injections possess a shelf life of 36 months, each receiving a score of 1.5 points, whereas eculizumab injection has a shelf life of 30 months, earning it a score of 1 point.

The results of the scoring for the pharmaceutical properties are summarized in Table 2.

Efficacy

Indications

All monoclonal antibodies are indicated for the treatment of NMOSD in patients who test positive for AQP4 antibodies. Notably, eculizumab has received approval for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), which contributes to its higher efficacy score of 5 points, while the other two monoclonal antibodies each garnered 4 points.

Table 2 Results of Pharmacological Properties Scoring

Pharmaceutical Properties (28 Points)		**Grading Criteria**	**Eculizumab**	**Inebilizumab**	**Satralizumab**
Pharmacological effects (5)	Definite clinical efficacy, precise mechanism of action, and innovative mechanism of action or target point of action	5	5	5	5
	Definite clinical efficacy and precise mechanism of action	4			
	Fair clinical efficacy and mechanism of action are unclear	2			
	General clinical efficacy and unclear mechanism of action	1			
In vivo processes (5)	Well-defined in vivo process with complete pharmacokinetic parameters	5	5	5	5
	Well-defined in vivo process with incomplete pharmacokinetic parameters	3			
	In vivo processes are unclear, or no pharmacokinetic studies are available	1			

(*Continued*)

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Table 2 (Continued).

Pharmaceutical Properties (28 Points)		Grading Criteria	Eculizumab	Inebilizumab	Satralizumab
Pharmacy and methods of use (multiple choice) (12)	Main ingredients and excipients (all specify 2; one specify 1)	2	2	2	2
	Specification and packaging (all appropriate for clinical use/dose adjustment 2; one appropriate 1)	2	2	2	2
	Dosage forms (oral/inhalation/topical formulations 2; subcutaneous/intramuscular injections 1.5; intravenous drip/intravenous injections 1)	2	1	1	1.5
	The dose administered (fixed dose 2; dose to be adjusted during use 1.5; dose based on body mass or body surface area 1)	2	1.5	1.5	1.5
	Frequency of administration (<1 dose/d 2; 2 doses/d 1.5; ≥3 doses/d 1)	2	2	2	2
	Ease of use (self- administration without assistance 2; with help or training 1.5; administered by medical personnel 1)	2	1	1	1
Storage conditions (multiple choice) (4)	Storage at room temperature	3			
	Storage in the shade	2			
	Refrigerated/frozen storage	1	1	1	1
Expiry date (2)	No need for shade/light protection	1			
	>60 months	2			
	≥36 months, <60 months	1.5		1.5	1.5
	≥24 months, <36 months	1	1		
	≥12 person-months, <24 months	0.5			
	<12 months	0.25			
Pharmaceutical Properties Score			21.5	22	22.5

Clinical Guidelines

Monoclonal antibodies are endorsed for use in AQP4-positive NMOSD patients according to both domestic and international clinical guidelines. National guidelines recommend all three monoclonal antibodies for long-term management, assigning an evidence level of I A,[1] whereas Japanese guidelines assign a level of II C.[14] Although other consensus statements and expert recommendations do not specify clear levels of endorsement, they consistently affirm the effectiveness and safety of these treatments in AQP4-positive NMOSD patients. Consequently, all three monoclonal antibodies received a score of 12 points. A summary of domestic and international guidelines or consensus recommendations is presented in Table 3.

Clinical Efficacy

The existing literature establishes the annualized relapse rate (ARR) as the primary efficacy endpoint, while the secondary endpoint focuses on disability progression, assessed via the expanded disability status scale (EDSS) score before and after treatment. Randomized controlled trials (RCTs) have evaluated the efficacy and safety of monoclonal

Table 3 Recommendations From National and International Guidelines/Consensus

Name of the Guidelines	Guide Developers and Sources	Name of Drug	Recommended Content	Level of Evidence
Clinical practice guidelines for multiple sclerosis, neuromyelitis optica spectrum disorder, and myelin oligodendrocyte glycoprotein antibody-associated disease 2023 in Japan[14]	Multiple Sclerosis and Neuromyelitis Optica Spectrum Disorder Guideline Development Committee	Eculizumab Inebilizumab Satralizumab	Patients diagnosed with NMOSD who test positive for AQP4 antibody are advised to commence treatment with biological agents for attack prevention. However, a careful evaluation is necessary for patients requiring treatment initiation with biological agents.	II C
Guidelines for Diagnosis and Treatment of Neuromyelitis Spectrum Diseases in China (2021 Edition)[1]	Neuroimmunology Branch of the Chinese Society of Immunology	Eculizumab Inebilizumab Satralizumab	Satralizumab monotherapy or in combination with traditional immunosuppressants can significantly delay the recurrence time of AQP4 IgG positive NMOSD patients; Inalizumab can significantly reduce disease recurrence and slow down disability progression in patients with NMOSD; Ecuzumab monotherapy or combination with traditional immunosuppressants can significantly reduce disease recurrence in AQP4 IgG positive patients	I A
International Delphi Consensus on the Management of AQP4-IgG+ NMOSD Recommendations for Eculizumab, Inebilizumab, and Satralizumab[5]	International panel of clinical experts in NMOSD	Eculizumab Inebilizumab Satralizumab	A total of 25 practical expert recommendations related to the treatment of AQP4 IgG positive NMOSD patients with eculizumab, Inelizumab, or satralizumab were generated	/
Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management[38]	Neuromyelitis Optica Study Group	Eculizumab Inebilizumab Satralizumab	Initiation and selection criteria: Eculizumab / ravulizumab, inebilizumab, rituximab, satralizumab and tocilizumab are highly effective therapies for AQP4-IgG-positive NMOSD. While there is no high-level evidence demonstrating the superiority of one drug over another, each is suitable for different clinical needs and situations. Long-term immunotherapy in AQP4-IgG-positive NMOSD should be initiated with one of the monoclonal antibodies eculizumab/ ravulizumab, inebilizumab, rituximab, or satralizumab, whenever those are available and accessible. Switching drugs: In case of treatment failure with classical immunosuppressive therapies, therapy should be switched to a monoclonal antibody. In case of treatment failure with a monoclonal antibody, therapy should be switched to another monoclonal antibody, preferably with a different mode of action.	/

(*Continued*)

Table 3 (Continued).

Name of the Guidelines	Guide Developers and Sources	Name of Drug	Recommended Content	Level of Evidence
Update on diagnosis and treatment of neuromyelitis optical spectrum disorders (NMOSD)-recommendations of Section of Multiple Sclerosis and Neuroimmunology of Polish Neurological Society[41]	Polish Neurological Society	Eculizumab Inebilizumab Satralizumab	Drugs used in seropositive NMOSD in which the following antibodies show high efficacy (they can be used as the first-line treatment): eculizumab (ECZ) i.v. as monotherapy inebilizumab (IBZ) i.v. as monotherapy satralizumab (STZ) s.c. as monotherapy or combination therapy with other immunosuppressive drugs (eg corticosteroids, AZA, or MMF)	/
Pregnancy and neuromyelitis optica spectrum disorders: 2022 recommendations from the French Multiple Sclerosis Society[42]	AFSEP, French multiple sclerosis society	Eculizumab	Women of childbearing potential have to use effective contraception during treatment and up to 5months after treatment. Eculizumab should be given to a pregnant woman only if clearly needed. Breastfeeding should be discontinued during treatment and up to 5months after treatment.	/

antibodies, with all studies affirming their effectiveness and safety.[15–26] However, it is important to note that there are currently no direct RCT comparisons among the monoclonal antibody therapies. Conducting "head-to-head" or direct comparative studies with placebo controls is particularly challenging in the context of rare diseases, leading to the publication of multiple indirect meta-analyses.

A network meta-analysis indicated that eculizumab is superior to inebilizumab and satralizumab in reducing the risk of recurrence; it also demonstrated that eculizumab is more effective than satralizumab in lowering the annual recurrence rate, and that it outperforms both satralizumab and inebilizumab in improving disability progression.[7] Another network meta-analysis corroborated that eculizumab is associated with a reduced risk of relapse compared to satralizumab and inebilizumab.[27] Furthermore, subgroup analyses within the meta-analysis suggested that eculizumab may be more effective than other monoclonal antibodies in decreasing the risk of relapse among AQP4-positive patients.[28]

In summary, for the primary outcome endpoint, eculizumab, inebilizumab, and satralizumab received scores of 6, 5, and 5 points, respectively. For the secondary outcome endpoint, the scores were 4, 3, and 4 points, respectively. The results of the efficacy scoring are detailed in Table 4.

Table 4 Efficacy Score Results

Efficacy (27 points)		Grading Criteria	Eculizumab	Inebilizumab	Satralizumab
Indications (5)	Clinically necessary, preferred	5	5		
	Clinical need, second choice	3		4	4
	More medicines available	1			

(*Continued*)

Table 4 (Continued).

Efficacy (27 points)		**Grading Criteria**	**Eculizumab**	**Inebilizumab**	**Satralizumab**
Recommended Guidelines (12)	Diagnosis and treatment norms/clinical pathways, consensus issued by national health administrative agencies/management methods, etc., guideline level I recommendation (Level A evidence 12; Level B evidence 11; Level C evidence, and others 10)	12	12	12	12
	Guidelines Level II and below (Level A Evidence 9; Level B Evidence 8; Level C Evidence and Others 7)	9			
	Expert Consensus Recommendations (the consensus published by the society organizations based on systematic evaluation 6; the consensus published by the society organization others 4)	6			
	Systematic evaluation/Meta-analysis (large sample, high-quality systematic evaluation/Meta-analysis 3; small sample, low-quality systematic evaluation/ Meta-analysis 2; systematic evaluation/Meta-analysis of non-RCT studies 1).	3			
Clinical efficacy (10)	The primary efficacy endpoint indicators	6	6	5	5
	The secondary efficacy endpoint indicators	4	4	3	4
Effectiveness Score			27	24	25

Safety

The safety evaluation was conducted through four distinct dimensions: grading of adverse reactions utilizing the Common Terminology Criteria for Adverse Events (CTCAE-V5.0) (8 points), considerations for special populations (11 points), assessment of adverse reactions attributable to drug interactions (3 points), and miscellaneous factors (3 points).

Adverse Reactions

Safety data pertaining to the medications were gathered through a comprehensive review of both domestic and international literature, drug package inserts, and official communications from regulatory bodies (eg, FDA and NMPA websites). The severity of adverse reactions was assessed in accordance with the CTCAE-V5.0 grading system. The most frequently reported adverse reactions associated with eculizumab include upper respiratory tract infections, nasopharyngitis, and headaches, predominantly occurring during the initial treatment phase, with a majority classified as mild to moderate in severity and an average incidence ranging from 1% to less than 10%, thus earning 2 points. The most severe adverse reaction identified was life-threatening or fatal meningococcal infection, with an incidence of 10% to less than 1%, which earned 3 points. For inebilizumab, the most common adverse reactions include urinary tract infections (20%), nasopharyngitis (13%), infusion-related reactions (12%), arthralgia (11%), and headaches (10%), primarily mild to moderate, resulting in 1 point. Severe adverse reactions, such as neutropenia, occurred with an incidence of 1% to less than 10%, earning 2 points. Satralizumab's most prevalent adverse reactions are weight gain and elevated transaminases, generally mild to moderate in severity. Severe adverse reactions include nasopharyngitis (12%) and cellulitis (10%), which earned 1 point. It is crucial to highlight that these three monoclonal antibodies, as primary immunosuppressants, necessitate that all NMOSD patients receive vaccinations in accordance with the current immunization guidelines prior to initiating treatment to minimize infection risk.

Special Populations

Pediatric Patients

Eculizumab and inebilizumab have not established safety and efficacy profiles in pediatric populations, and the absence

of reliable literature precludes the assignment of points. Satralizumab has not been evaluated in patients under 12 years of age but is deemed applicable for those over 12 years, earning 0.5 points.

Elderly Patients

No significant differences in safety profiles between elderly and younger patients have been reported for the three monoclonal antibodies. Pharmacokinetic analyses in patients with NMOSD did not reveal age-related effects for satralizumab, which was therefore assigned 0.5 points with caution.

Pregnancy and Lactation

The existing evidence regarding the three monoclonal antibodies in the context of NMOSD is insufficient. Although limited data have not indicated an increased risk of fetal malformations or fetal-neonatal toxicity, the lack of well-designed comparative studies leaves considerable uncertainty. Consequently, all three agents received no points. Similarly, there is a lack of reliable data supporting their use in lactating women, resulting in no points awarded.

Hepatic Insufficiency

Satralizumab is recommended for use with close monitoring of liver function, earning 1 point. The other two monoclonal antibodies have not been investigated in patients with hepatic insufficiency, thus receiving no points.

Renal Insufficiency

Eculizumab does not necessitate dose adjustments in patients with renal insufficiency, earning 3 points. Conversely, inebilizumab and satralizumab have not been formally studied in individuals with renal impairment, resulting in no points awarded.

Adverse Reactions Associated with Drug Interactions

None of the three monoclonal antibodies have been subjected to formal studies assessing drug interactions. Nevertheless, the concurrent administration of these antibodies with immunosuppressive agents, such as systemic corticosteroids, may elevate the risk of infections. It is essential to consider the potential for additive immunosuppressive effects when monoclonal antibodies are used in conjunction with immunosuppressive therapies. Consequently, all three antibodies were assigned a score of 2 points.

Other Considerations

While the majority of adverse reactions associated with the drugs under consideration were reversible and classified as mild to moderate, certain severe adverse reactions may have enduring consequences for patients, resulting in a score of 0 points. None of the three monoclonal antibodies have undergone testing for carcinogenicity, which also resulted in a score of 0 points. In terms of reproductive toxicity, eculizumab has not been evaluated, leading to a score of 0 points. Although inebilizumab and satralizumab have not demonstrated adverse effects on the growth and development of offspring, the potential for compromised immune function in these offspring warrants a score of 0 points for both. Additionally, inebilizumab, as a monoclonal antibody targeting CD19, has a significant impact on the continuous depletion of B cells and sustained reduction in immune function, which may cause adverse prognosis to patients. Eculizumab carries a black box warning regarding the risk of severe meningococcal infections, whereas the other two monoclonal antibodies do not have any specific medication warnings.

The results of the safety scoring are detailed in Table 5.

Economy

An economic evaluation of drug therapies was performed by comparing the daily treatment costs of selected medications with those of drugs sharing the same generic name and alternative therapies indicated for the primary condition. Data regarding drug pricing were sourced from the National Drug Centralized Procurement Platform, the Sunshine Procurement Platform, corporate websites, the NMPA, and the National Healthcare Security Administration, with the

Table 5 Results of Safety Scoring

Safety (25 points)		Grading Criteria	Eculizumab	Inebilizumab	Satralizumab
Moderate adverse reactions (3)	Incidence <1%	3			
	Incidence 1% to <10%	2	2		2
	Incidence ≥10%	1		1	
	ADR occurrence data not available	0			
Severe adverse reactions (5)	Incidence < 0.01%	5			
	Incidence 0.01%~<0.1%	4			
	Incidence 0.1%~<1%	3	3		
	Incidence 1% to <10%	2		2	
	Incidence ≥10%	1			1
	ADR occurrence data not available	0			
Special populations (multiple choice) (11)	Available for children (both 2; 1.9 for 3 months+; 1.8 for 6 months+; 1.7 for 9 months+; 1.6 for ages 1+; 1.5 for ages 2 +; 1.4 for ages 3+; 1.3 for ages 4+; 1.2 for ages 5+; 1.1 for ages 6+; 1.0 for ages 7+; 0.9 for ages 8+; 0.8 for ages 9+ 0.7 for ages 10+; 0.6 for ages 11+; 0.5 for ages 12+.	2	0	0	0.5
	The elderly (available 1; use with caution 0.5)	1	0	0	0.5
	Pregnant women (early pregnancy 1; during the first trimester 0.8; during the second trimester 0.5).	1	0	0	0
	Lactating women (available 1; use with caution 0.5)	1	0	0	0
	Hepatic dysfunction (severe available 3, moderate available 2. Lightly available 1)	3	0	0	1
	Renal dysfunction (severe available 3, moderate available 2. Lightly available 1)	3	3	0	0
Adverse reactions due to drug interactions (3)	No dosage adjustment is required	3			
	Dosage adjustment required	2	2	2	2
	Prohibited to use at the same time	1			
Other (multiple choice) (3)	Reversibility of adverse reactions	1	0	0	0
	Non-teratogenic/ non-carcinogenic	1	0	0	0
	No special medication warnings	1	0	1	1
Total Safety Score			10	6	8

information being current as of April 1, 2025. Given the substantial expense associated with biologic therapies and the prolonged maintenance treatment required for patients with NMOSD, we assessed the dosing regimens pertinent to maintenance therapies. The good news is that biosimilars of certain monoclonal antibodies, such as Bkemv and Epysqli, which are biosimilars of eculizumab, although not yet available in China, have been approved by the FDA in 2024 for the treatment of NMOSD. These are much cheaper alternatives and may benefit more patients in the future, at which point economic evaluations will also be dynamically adjusted. Currently, in evaluating the comparability of generic drugs, all

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three monoclonal antibodies—inebilizumab, eculizumab, and satralizumab—received a score of 3 points due to the lack of identical generic names. For the assessment of therapeutic alternatives based on primary indications, the scoring formula utilized was: Score = (Lowest daily treatment cost / Evaluated drug's daily treatment cost) × 7. Inebilizumab (AstraZeneca Nijmegen B.V)., which exhibited the lowest daily cost of ¥352.29, achieved the highest score of 7. The other agents were scored as follows: eculizumab received 3.43 points, while satralizumab garnered 5.6 points. Detailed information can be found in Tables 6 and 7.

Other Attributes

National Health Insurance and Essential Drugs

All three monoclonal antibodies are incorporated into the negotiated drug section of the National Health Insurance catalog, categorized as Category B, which entails payment limitations. While eculizumab is listed in the catalog, it is not reimbursed for patients with NMOSD, thus receiving a score of 1 point. In contrast, inebilizumab is covered for adult patients who are positive for AQP4 antibodies, and satralizumab is covered for adolescents aged 12 years and older, as well as adults with AQP4 antibody-positive NMOSD, each earning a score of 1.5 points.

National Centralized Drug Procurement and Originator Drugs

None of the three monoclonal antibodies are part of the national centralized drug procurement initiative, resulting in a score of zero. However, all three are classified as originator drugs, each earning 1 point.

Manufacturer Status

The manufacturers of eculizumab and inebilizumab rank among the top ten pharmaceutical companies globally (ranked 8th in 2024), thereby earning 1 point each. Conversely, satralizumab is produced by a company ranked 43rd among the top 50 global pharmaceutical firms, resulting in a score of 0.2 points.

Table 6 Basic Economy Information

	Eculizumab	Inebilizumab	Satralizumab
Specification	300 mg/30 mL	100 mg (10 mL)/vial	120 mg (1 mL)/vial
Dosage*	1200 mg every 14 days	300 mg every 6 months	120 mg every 4 weeks
Daily Treatment Cost (¥)	719.43	352.29	404.21

Notes: *Calculated based on maintenance dosage.

Table 7 Economy Score Results

Economy (10 Points)		Grading Criteria	Eculizumab	Inebilizumab	Satralizumab
Same Generic Name Drug (3)	Daily treatment cost of the lowest-priced drug is 3 points; Evaluation drug score = Lowest daily treatment cost / Evaluation drug daily treatment cost × 3	3	3	3	3
Alternative Drugs for Primary Indication (7)	Daily treatment cost of the lowest-priced drug is 7 points; Evaluation drug score = Lowest daily treatment cost / Evaluation drug daily treatment cost × 7	7	3.43	7	5.63
Total Score for Economics			6.43	10	8.63

Global Usage

Research concerning biological agents for NMOSD patients has garnered significant attention in recent years. Although the three monoclonal antibodies have not been available for an extended period, the evidence supporting their efficacy and safety is progressively accumulating, and they have been introduced and marketed in China, the United States, Europe, and Japan. The scores for the other attributes are presented in Table 8.

The scores derived from this drug rating tool fluctuate based on factors such as drug prices, health insurance coverage, updates to the essential medicines list, modifications to the bulk procurement list, and shifts in pharmaceutical company development. These evaluation metrics are dynamic and require regular updates to ensure the most current scores are maintained.

Table 8 Results of Other Attributes Scoring

Other Attributes (10 Points)		**Grading Criteria**	**Eculizumab**	**Inebilizumab**	**Satralizumab**
National Health Insurance (3)	National medical insurance category A, no payment restrictions	3			
	National medical insurance category A with payment restrictions	2.5			
	National medical insurance category B, no payment limitations	2			
	National medical insurance category B with payment restrictions.	1.5		1.5	1.5
	Not on the national medical insurance list	1	1		
National Essential Drugs (3)	National essential drugs without Δ requirement	3			
	National essential drugs with Δ Requirements	2			
	Not on the national essential drugs list	1	1	1	1
National Centralized Drug Procurement (1)	Selected drugs for centralized national procurement	1	0	0	0
Originator/ Reference/ Consistency Evaluation (1)	Drug of origin/reference drug	1	1	1	1
	Generic drugs through consistency evaluation	0.5			
Manufacturer Status (1)	The world's top 50 pharmaceutical manufacturers in terms of sales volume (1 for top 1–10; 0.8 for top 11–20; 0.6 for top 21–30; 0.4 for top 31–40; 0.2 for top 41–50) / Top 100 Pharmaceutical Industry published by MIIT (1for top 1–20; 0.8 for top 21–40; 0.6 for top 41–60; 0.4 for top 61–80; 0.2 for top 81–100).	1	1	1	0.2
Global Usage (1)	Available in China, USA, Europe, Japan	1	1	1	1
	Domestic and international sales	0.5	0.5	0.5	0.5
Total Score for Other Attributes			5.5	6	5.2

Notes: The "Δ" sign indicates that the drug should be used by a physician with corresponding prescription qualifications or under the guidance of a specialist physician, and use monitoring and evaluation should be strengthened.

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Discussion

Significance of the Assessment

The guide has undergone a revision and refinement of the evaluation indicators pertinent to drug assessment and selection within medical institutions. This enhancement facilitates a quantitative scoring system that more accurately reflects the prioritization of drugs in accordance with national policy mandates. The scoring criteria have been made more detailed, explicit, and actionable. By quantifying scores across five dimensions—pharmacological properties (28 points), efficacy (27 points), safety (25 points), economics (10 points), and other attributes (10 points)—this study seeks to provide an objective framework for the selection and evaluation of drugs entering and exiting medical institutions.

Monoclonal antibody therapies are pivotal in the management of tumors, autoimmune disorders, and rare diseases due to their high specificity and notable efficacy. Recently, their significance has escalated in the treatment of patients with NMOSD. However, the substantial costs associated with these therapies, coupled with their complex safety profiles, underscore the necessity for urgent evaluations concerning their efficacy, safety, and economic viability. To date, the literature lacks comprehensive evaluation studies utilizing "The Second Edition" to compare eculizumab, inebilizumab, and satralizumab. Furthermore, these biological agents are a primary focus of the guide, and there was an urgent need for rapid and thorough evaluations to inform their selection.

Description of the Assessment and Analysis of Results

As presented in Table 9, the final quantitative scores for the evaluated drugs, arranged in descending order, are as follows: eculizumab (70.43), satralizumab (69.33), and inebilizumab (68.00). According to the referenced guidelines,[11] the quantitative scoring system operates on a scale of 100 points. Scores exceeding 70 are classified as strongly recommended, while those ranging from 60 to 70 are considered weakly recommended or not recommended, depending on the availability of alternative treatment options. In light of the comprehensive evaluation results, eculizumab, which achieved a score above 70, is strongly endorsed for inclusion in hospital formularies. Conversely, the scores for the other two monoclonal antibodies fall below 70, suggesting that despite notable advancements in the research and application of biological targeted therapies for the treatment of NMOSD, these monoclonal antibodies continue to encounter challenges related to safety, treatment costs, and long-term efficacy, primarily due to their limited duration of clinical use.

Eculizumab has been identified as the most effective treatment option, receiving the highest overall score. This recombinant humanized IgG4 monoclonal antibody functions as a terminal complement protein C5 inhibitor, preventing the cleavage of C5 into its active fragments, C5a and C5b. Consequently, it obstructs the complement cascade, thereby mitigating astrocyte damage and neuronal injury.[29,30] Eculizumab is indicated for a variety of conditions, including NMOSD, paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and refractory generalized myasthenia gravis (gMG) in patients who are positive for anti-acetylcholine receptor (AChR) antibodies. Meta-analyses indicate that eculizumab outperforms two other monoclonal antibodies in terms of reducing the risk of relapse and improving disability progression,[7] Notably, it does not necessitate dose adjustments for patients with renal

Table 9 Final Total Score Results

Evaluation Dimension	Eculizumab	Inebilizumab	Satralizumab
Pharmaceutical Properties	21.5	22	22.5
Efficacy	27	24	25
Safety	10	6	8
Economy	6.43	10	8.63
Other Attributes	5.5	6	5.2
Total Score	70.43	68	69.33

insufficiency, however, it is associated with high costs and is not covered by health insurance for NMOSD patients. Additionally, it carries a black box warning due to the risk of potentially life-threatening meningococcal infections, with severe cases reported despite vaccination against meningococcal and Neisseria gonorrhoeae.[31,32] Satralizumab, a humanized IgG2 subtype recombinant anti-IL-6R monoclonal antibody, inhibits lymphocyte inflammation by blocking IL-6R signaling and is characterized by a low incidence of adverse reactions. It is indicated for NMOSD patients aged 12 years and older and offers relatively favorable economic benefits. Two pivotal clinical trials have demonstrated that satralizumab is effective in patients who are positive for AQP4-IgG, whether used as monotherapy or in combination; however, it has shown ineffectiveness in AQP4-IgG-negative NMOSD patients.[24,25] Inebilizumab, a humanized IgG subtype CD19 monoclonal antibody, depletes B cells and CD19-expressing plasma cells, thereby inhibiting antibody and complement-dependent cytotoxicity.[33] Compared to the other two monoclonal antibodies, inebilizumab presents significant economic advantages, with the lowest average daily treatment cost. It received approval in the United States in 2020 for the treatment of adult NMOSD patients who are AQP4-IgG-positive and was included in China's health insurance catalogue as a Category B drug in March 2022, significantly alleviating the economic burden on NMOSD patients. In terms of efficacy, inebilizumab has been shown to significantly reduce disease relapses and slow the progression of disability in NMOSD patients,[22] its side effects primarily include infections and infusion-related reactions, which are generally mild to moderate and predominantly occur during the initial infusion.[34] Both satralizumab and inebilizumab, with accumulated scores ranging from 60 to 70, are considered weakly recommended, allowing medical institutions to make treatment decisions based on their specific circumstances. Given the recent market introduction and limited clinical application of these monoclonal antibodies, their rare or potential long-term adverse reactions require ongoing observation in clinical practice. The safety of the drugs will be further comprehensively evaluated based on long-term follow-up results. Additionally, due to insufficient data on these monoclonal antibodies in special populations, including children, pregnant women, and lactating women, our scoring results are not applicable to these groups. Future targeted studies in these populations will enhance clinical decision-making.

In conclusion, the three monoclonal antibodies exhibit distinct advantages and disadvantages concerning their indications, efficacy, and safety profiles. Medical institutions across various regions must undertake a thorough evaluation of economic factors and other relevant attributes. Currently, the administration of monoclonal antibodies incurs significant costs, necessitating considerations of long-term affordability. Other monoclonal antibodies, including rituximab, tocilizumab, and ravulizumab, are utilized in clinical settings for the treatment of NMOSD; however, they have not received approval from the NMPA and are thus employed off-label, with their efficacy and safety requiring further substantiation through future clinical trials.

Biological Characteristics and Clinical Implementation

The pathogenesis of NMOSD is mainly driven by humoral immunity, with cellular immunity also contributing. A key pathological feature is the production of autoantibodies against AQP4-IgG, which can be detected in 70% to 80% of NMOSD patients.[35] AQP4-IgG disrupts the blood-brain barrier (BBB) by binding to AQP4 on astrocytes, activating the classical complement pathway, leading to complement-dependent cytotoxicity (CDC). This results in the aggregation of granulocytes, eosinophils, and lymphocytes, subsequently causing astrocyte damage, myelin, and axonal injury, ultimately manifesting as clinical symptoms of NMOSD.[36] Ongoing studies on mechanisms have introduced novel approaches and targets for monoclonal antibody research. Compared to traditional immunosuppressive drugs, monoclonal antibodies have demonstrated certain advantages in preventing NMOSD. Presently, in the context of NMOSD pathogenesis and biological target therapies, including complement inhibitors, IL-6 receptor blockers, and B lymphocyte depleting agents, the representative drugs are eculizumab, satralizumab and inebilizumab/ rituximab (RTX).

RTX is a chimeric CD20 monoclonal antibody that depletes B cells to minimize plasma cell production, thereby reducing antibody generation and decreasing antibody-dependent cellular cytotoxicity. RTX significantly reduces relapses and slows the progression of neurological impairment in NMOSD. In China, RTX is still considered off-label use and was not included as the evaluation drug in this article. However, it is the first monoclonal antibody used for treating NMOSD and is recommended as a first-line or second-line long-term immunosuppressive treatment option for AQP4-IgG positive NMOSD patients in multiple guidelines and expert consensus statements.[1,25,37,38] Nonetheless, the

optimal treatment regimen remains uncertain. A meta-analysis suggests that RTX efficacy is not influenced by patient gender, age at onset, disease duration, initial symptoms, serum AQP4 antibody status, or follow-up time. However, it may be associated with race and prior immunosuppressive therapy, with patients who have not undergone immunosuppressive therapy potentially experiencing better outcomes.[39] Despite the promising efficacy of emerging monoclonal antibodies, RTX retains significant importance due to its extensive clinical validation, abundant real-world data, relatively low cost (especially post-patent expiration), and longer dosing interval (typically one infusion every six months). This makes it particularly suitable for resource-limited regions or specific clinical scenarios.

Eculizumab is a monoclonal antibody that specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage into C5a and C5b and preventing the formation of the terminal complement complex C5b-9. It exhibits rapid onset and provides sustained near-complete inhibition of C5 activity after the first infusion. Extensive clinical trials have shown that it significantly reduces disease recurrence in AQP-4 Ig-positive patients, whether used alone or in combination with conventional immunosuppressants.[19,40] The safety data for long-term eculizumab treatment of NMOSD (over 5 years) primarily originates from other indications. In this study, eculizumab achieved the highest comprehensive score (70.43), showing advantages in reducing relapse risk, lowering annualized relapse rate, and improving disability progression, making it suitable as a first-line drug recommendation. It should be noted that adherence to the meningococcal vaccination protocol is required.

Inebilizumab and satralizumab scored between 60–70 points. Due to their recent market entry, they have limited observation periods. Inebilizumab, a humanized monoclonal antibody, selectively targets and depletes CD19-positive B cells and pre-B cell subsets. Its efficacy and safety in treating NMOSD were confirmed through a multinational, multicenter Phase III randomized controlled placebo trial (n-momentum) and its subsequent open-label extension study (OLE).,[20–22] However, it should be noted that there is a significant risk of severe infection due to potential deep B-cell depletion (especially low IgG levels and opportunistic infections). Additionally, the long-term safety is unknown, and it has high costs. In this study, inebilizumab received an overall score of 68 points. For patients with limited economic resources and access to CD19+ B-cell monitoring, it presents a more viable option. Satralizumab is a humanized monoclonal antibody that inhibits IL-6-mediated signaling by binding to both soluble and membrane-bound IL-6 receptors. It features a long half-life and a slow onset of action. Research has demonstrated that the clinical onset for efficacy of satralizumab is 8–12 weeks.[24,25] With frequent dosing every four weeks, an increased infection risk, and high costs. In this study, satralizumab scored 69.33 overall. For Pediatric-onset NMOSD (ages 12–17), satralizumab is an appropriate treatment option. Furthermore, subcutaneous administration is one of its advantages. When selecting different monoclonal antibodies in clinical practice, it is essential to strictly evaluate individual patient circumstances (such as history of infection risk, baseline immune status, disease activity, concomitant medications, economic capacity, and administration preference) and weigh the benefits and risks.

Furthermore, innovative therapeutic agents for NMOSD are currently undergoing clinical trials, such as MIL62 (NCT05314010), a third-generation CD20 antibody developed by Beijing Tianguangshi; Daratumumab (NCT05403138), an anti-CD38 monoclonal antibody produced by Johnson & Johnson; and Belimumab (NCT05154734), an inhibitor of B lymphocyte stimulator (BLyS/BAFF). These advancements are expected to expand the range of clinical treatment options in the future, with the addition of more emerging targeted drugs, more medications can also undergo rapid comprehensive evaluations through "The Second Edition", facilitating dynamic adjustments to the drug catalog.

Global Implementation Considerations

This rapid, comprehensive evaluation of three monoclonal antibodies for NMOSD treatment utilizes a scoring tool based on "The Second Edition" guidelines. This scoring system can serve as a reference for pharmaceutical evaluations and selections by medical institutions both domestically and internationally, including assessments of chemical drugs and biologics. When applying this model to other countries or regions, local policies and actual needs should be considered to make appropriate adjustments to the evaluation criteria and weights. For instance, indicators such as drug economics, essential medicines lists, national health insurance directories, and bulk procurement drug lists may be specific to China. However, dimensions like pharmacological characteristics, efficacy, and safety, along with their respective standards and weight criteria, can generally be applied in other regions. During weight adjustments, controversial issues can be resolved

through the Delphi method to reach consensus recommendations. Given the high cost of all three monoclonal antibodies used for NMOSD, cost and drug accessibility may become critical factors in drug selection. Therefore, it is necessary to combine regional income stratification with the scoring results. It is important to note that when using this model to quantitatively evaluate drugs, whether domestically or in other regions, attention should be paid to changes in drug-related information. If certain drugs receive new indications, new guideline recommendations, or higher-level evidence emerges, or if there are changes among similar drug varieties, or if there are updates to the National Essential Medicines List, the National Health Insurance Directory, or the National Negotiated Drug List, the scores for those drugs should be dynamically adjusted accordingly.

Shortcomings and Limitations

This study has some limitations: 1. Despite improvements made in "The Second Edition" of the guide, certain scoring criteria remain imperfect in practical application, and the evaluation process may exhibit a degree of subjectivity. For instance, the primary and secondary efficacy endpoints utilized in drug efficacy assessments are numerous and inconsistent across the literature. 2. The scoring outcomes derived from this tool are dynamic and may require updates to reflect changes in the drug catalog, particularly concerning economic factors (eg, centralized volume-based procurement, nationally negotiated drugs), necessitating ongoing monitoring of the latest policies to adjust scores accordingly. 3. Given the rarity of the diseases in question, the number of subjects eligible for inclusion in clinical studies is often limited, and these monoclonal antibodies have only recently entered the market. Consequently, they may initially receive lower scores within this guide's scoring system due to their absence from established guidelines or expert consensus. As guidelines, expert consensus, and reports of adverse reactions are updated, the final scores derived from this guide may be subject to change. 4. As a rare disease, NMOSD has a very limited number of eligible participants for clinical studies. Currently, there is a scarcity of "head-to-head" trials comparing monoclonal antibodies directly or placebo-controlled studies. Efficacy assessments often rely on indirect comparisons from published meta-analyses. However, due to the limited number and quality of available studies, further validation through high-quality clinical trials is essential. Should higher-level evidence-based conclusions evolve, efficacy scores may require revision.

Conclusion

This article conducted a rapid comprehensive evaluation of three monoclonal antibodies for treating NMOSD using a scoring framework based on the "The Second Edition" guidelines. The results showed that eculizumab scored 70.43, satralizumab scored 69.33, and inebilizumab scored 68 out of a maximum of 100 points. The extensive evaluation of scoring outcomes indicated that eculizumab achieves the highest overall score, thereby establishing its suitability for inclusion as a standard medication within hospital formularies. Both satralizumab and inebilizumab possess distinct attributes, prompting a recommendation for medical institutions to adapt their drug formularies dynamically, taking into account departmental characteristics, patient requirements, and financial constraints. The drug scores obtained using this rating tool are variable and need to be updated when necessary. When selecting different monoclonal antibodies for clinical use, a comprehensive assessment of the patient's individual circumstances is required, including infection risk history, baseline immune status, disease activity, concomitant medications, economic capacity, and administration preferences, and the benefits and risks must be weighed. This health technology assessment offers evidence-based guidance for the selection and judicious utilization of biological agents, including monoclonal antibodies, and may also serve as a reference for hospitals in other nations in their drug selection processes.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically

reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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