国际中医临床实践指南 睑板腺功能障碍
国际组织标准编制说明

Formulation Explanations

一、工作简况

主要起草单位：湖南中医药大学第一附属医院、中国中医科学院眼科医院、山东中医药大学附属医院、山东中医药大学附属眼科医院。

参与起草单位：中国中医科学院眼科医院、山东中医药大学附属医院、山东中医药大学附属眼科医院、福建中医药大学附属人民医院、成都华蜀眼科医院、山西省眼科医院、成都中医药大学眼科学院/附属银海眼科医院、北京中医药大学第三附属医院、上海交通大学医学院附属同仁医院、中日友好医院、西安市中医医院、天津中医药大学附属医院、中国中医科学院、上海中医药大学附属龙华医院、首都医科大学附属北京同仁医院、上海中医药大学附属曙光医院、广东中医院、广州中医药大学第二附属医院、广西中医药大学第一附属医院、辽宁中医药大学附属第二医院、黑龙江中医药大学第一附属医院、上海交通大学附属第一人民医院、北京中医药大学东直门医院、河北省眼科医院、河南省中医院、湖北省中医院、贵州中医药大学第二附属医院、北京中医药大学东方医院、山东中医药大学、台湾中国医药大学新竹附设医院、香港大学、香港苏瑞冰中医诊所、Wellspring clinic, Vancouver BC,Canada（加拿大）、新加坡中华医院、美国 NEI/NIH、American Learning and Vision Association（美国）、针灸保健学会（美国）、St.Olav Eye Clinic（挪威）、日中健康科学会。

主要起草人：陈向东、毕宏生、段俊国、郝晓凤、谢立科、宋继科、秦裕辉、颜家朝。

参与起草人：

中　　国：陈美荣、陈莹山、程娟、陈来华、付美林、何萍、蒋炎云、江婕妤、接传红、金明、刘光辉、刘莉、Calvin C.P. Pang（彭智培）、李建超、梁风鸣、刘绍燕、刘倩宏、刘新泉、罗光雄、罗继红、马东丽、缪晚虹、庞龙、苏瑞冰、孙河、吴星伟、王方、温莹、吴西西、许家骏、WaiChu（朱伟杰）、张铭连、周剑、朱晓林、庄曾渊、左韬、张风梅。

加 拿 大：于卫东。

新 加 坡：林秋霞。

美　　国：Quan Dong Nguyen（阮全东）、周悦、Andy Rosenfarb、Christina Jia Qi Bi。

挪　　威：Erik VinjeOlbjorn、Ole Jorgen Frydenlund。

日　　本：仝选甫。

二、标准起草过程简介

（如：何时启动，如何开展调研，如何征求各利益相关方的意见，召开了哪些审稿会，标准审定委员会讨论或投票情况等）

1 指南编制原则

《国际中医临床实践指南 睑板腺功能障碍》制定遵循了“循证为举，共识为主，经验为鉴”的原则，指南的编制程序、方法和结构，借鉴了国际上通用的临床实践指南的制定方法，不仅保证了指南制作的科学性，又体现了中医药临床实践特色。本指南编制全程基于证据检索和广泛的专家意见调研，并层层深入研讨和分析，所有过程和环节均可以溯源，实现了有据可循。

2 主要工作过程

2.1 启动部署阶段

本文件已在世界中医药学会联合会立案和申请后确定指南名称和具体内容，目前《国际中医临床实践指南 睑板腺功能障碍》(SCM/NP2025-200)在世界中医药学会联合会立项 。

2.2 起草阶段

2.2.1 指南起草组的成立

通过负责人召集，与相关专业领域专家电话及信息沟通确定项目组成员。

2.2.2 组织管理

本文件制定过程开通了微信工作群，主要有共识专家和工作组成员组成。考虑到时效化，日常工作主要通过网络会议、电话联系等方式进行，定期召开内部讨论会和网络交流会，并将每次会议进行记录和存档。

2.2.3 避免利益冲突

凡参与制定工作的成员均已声明未存在利益冲突，未发现任何明确和本文件主题相关商业、专业或其他方面的利益，以及所有可能被本文件成果影响的利益冲突情况。

2.3 确定主题和范围

指南题目：国际中医临床实践指南 睑板腺功能障碍。

范围：本文件规定了睑板腺功能障碍的中医术语和定义、诊断、辨证和治疗等。本文件适用于中医眼科临床从业医师对睑板腺功能障碍的诊断和治疗依据，中西医结合、 西医眼科从业医师和其他学科中医师也可参照本文件相关内容。

2.4 构建指南问题

2.4.1 专家访谈

2.4.1.1 访谈方案确定过程及方法

访谈专家为具有丰富工作经验的临床专家，主要研究方向为中医治疗睑板腺功能障碍。本次专家访谈以线上会议访问的形式进行，受访专家数目应标准要求共5人。访谈提纲的起草由起草专家组专家指导，起草组成员具体完成。

2.4.1.2 受访专家名单

以表格形式列出。详见表1。

姓名	单位	职称	专业
毕宏生	山东中医药大学附属眼科医院	教授	中西医结合眼科
谢立科	中国中医科学院眼科医院	教授	中医眼科
郝晓凤	中国中医科学院眼科医院	教授	中医眼科
颜家朝	湖南中医药大学第一附属医院	副教授	中医眼科
刘光辉	福建中医药大学第一附属医院	教授	中医眼科

表1 专家名单

2.4.1.3 访谈提纲

《国际中医临床实践指南 睑板腺功能障碍》基础问题：

定义相关 ——**睑板腺功能障碍**的定义是什么？

《睑板腺功能障碍干预方案》临床问题：

诊断相关 —— **睑板腺功能障碍**诊断、辨证是什么？

治疗相关 —— **睑板腺功能障碍**的中医治疗有哪些？中医外治特色有哪些？

2.4.1.4 访谈结论

通过访谈初步确定了基础问题和临床问题，明确了睑板腺功能障碍范围、定义等基础问题、诊断与治疗的相关临床问题，专家们认同睑板腺功能障碍中医干预方式的优势。

姓名	访谈内容
毕宏生	睑板腺功能障碍有三层定义，目前缺乏适用于指导的诊断应参考相关指南标准
谢立科	中医治病的理念与西医的不同，睑板腺功能障碍的治疗应注重辨证论治，诊断部分内容与现行的有关专家共识及指南可能有一定重叠，本方案应注重创新性。
郝晓凤	治疗时，无形中带给社会一些焦虑。要体现出因人而治。
颜家朝	在各个地区，有很明显的趋势，有各种产品打着中医的旗号，非常期待中医指南能

	够细化，哪个阶段适合哪种方法？
刘光辉	中医的外治法在睑板腺功能障碍障碍的治疗中存在优势，应当如何规范化。

2.5 采用 PICO 原则确定检索策略

检索策略分为电子检索和手工检索，电子检索中文数据库包括 CNKI、VIP、SinoMed、WanFang Data;英文数据库包括 Medline、The Cochrane Library、 Embase、Clinical Trials gov.等。手工检索主要包括诊疗指南、标准、规范、药品 说明书、专利说明书、相关中西医眼科教材和专著，同时搜集未公开发表的科研 报告、学位论文、会议论文等灰色文献。检索时间均从建库截止至 2025 年 1 月。中文检索词包括：睑板腺功能障碍、干眼症、白涩症、中医药、中药、中草药、中成药等，英文检索词包括 Meibomian gland dysfunction, dry eye, white astringent, traditional Chinese medicine, Chinese herbal medicine, Chinese patent medicine 等。

2.6 证据筛选和资料提取

完成文献检索后，两位研究者通过阅读标题和摘要独立对文献进行了初步筛选，随后根据这些初筛后研究的全文进行了复筛，如存在分歧，则通过讨论或咨询第三方解决。

旨在研究某种干预缓解睑板腺功能障碍发生发展的证据均被纳入。纳入的研究类型包括：随机对照试验、队列研究、横断面研究、指南或专家共识等。任何可以体现缓解睑板腺功能障碍发生发展的指标都可以作为结局指标被纳入。无法获取全文的会议摘要被排除了。

2.7 现有证据的梳理

通过以上检索策略发现 5 篇相关指南，分别为 2013 中华医学会眼科学分会角膜病学组 《干眼临床诊疗专家共识（2013 年）》、我国睑板腺功能障碍诊断与治疗专家共识（2017 年）、中国睑板腺功能障碍专家共识：定义和分类（2023）、中国睑板腺功能障碍专家共识：诊断和治疗（2023）、中国干眼临床诊疗专家共识（2024 年）。另外，工作组还系统梳理了《国家基本医疗保险、工伤保险和生育保险药品目录（2017 年版）》、《国家基本药物目录》（2012 年版）（卫生部令第 93 号）、《中国药典》（2015 年版）有关治疗睑板腺功能障碍的中成药和饮片，对中医药治疗本病的相关古籍也进行了梳理，以及教材和医家著作进行了相关信息的提取。

2.8 制作新的系统评价

研究纳入标准:a.文献中明确提及“睑板腺功能障碍”、“干眼症”、“白涩症”；b.干预措施:

中成药、汤剂、针灸、中药熏洗；c.对照措施：西医常规治疗(睑板腺按摩、人工泪液、抗炎等)；d.主要结局指标：睑板腺功能、BUT 等；次要结局指标：中医证候评分等；e.研究设计类型：所有临床研究，但不做限定，优先考虑随机对照试验。研 究排除标准：重复发表；统计学方法有误；无法下载全文。

通过以上检索策略，共获得 959 篇文献，分别将检索所得题录输入 NoteExpress 3.5 文献管理软件进行查重，并从题录和摘要中进行初步筛选，将 符合标准的文献获取全文后再进一步鉴别筛选，最终获得 110 篇文献。文献筛选流程见图 1。

图 1 文件筛选流程

2.9 证据体质量评价

2.9.1 二轮改良的德尔菲法实现共识过程

采用改良的德尔菲法进行问卷调查，结合专家网络会议达成本指南的共识内容。遴选的共识专家成员为：与睑板腺功能障碍有关的临床一线专家：中西医师均有，以中医、中西医结合眼科医师为主，同时考虑到专家分布的地域性，涵盖国内 5 个省市 9 位专家。问卷调查时间:2024 年 10 月 10 日至 2024 年 12 月 10 日。两轮问卷主要针对指南中疾病诊断(发病情况、临床表现、 眼部检查、特殊检查)、鉴别诊断、中医证型和基于证据评价的所有治疗措施(方 药、中成药、耳穴贴压、针刺)进行评价。经过 2 轮改良的德尔菲法以及广泛的征求意见，本指南所有内容基本达成了共识。推荐强度确定的原则为:凡是对某项治疗措施强推荐人数超过总人数 75%，则强推荐使用该治疗措施；如果不推荐使用人数比例≥50%，则为不推荐；其他情况为弱推荐。

2.9.2 证据汇编存档

本指南在证据检索、筛选、评价等方面的具体操作过程及其所产生的本底资料均进行了汇总。

2.10 征求意见阶段

2.10.1 问卷征求意见

本指南在制定过程中开展了 2 轮专家会议、2 轮专家调查问卷，针对每轮会议及调查问卷的反馈意见，工作组成员进行了详细记录，并结合专家意见，深入讨论，进行修改。

2.10.2 世界中医药学会联合会网站征求意见

本指南在世界中医药学会联合会网站公开征求意见。

2.10.3 专家审核会征求意见

工作组负责人向专家汇报了本指南制定的情况和相关内容，以及向专家组提供了重点讨论的问题。会议结束，工作组总结专家意见， 并进行修改。

2.3.4 海外专家征求意见

本指南向海外专家征求意见。

三、主要技术内容介绍

（如：技术指标、参数、公式、性能要求、实验方法、检验规则等）的论据（包括试验、统计数据），修订标准时，应增加新、旧标准的对比。

1 指南制定依据

本指南的制定依据美国医学研究所(Institute of Medicine，IOM)2011 年对临床实践指南的最新定义（基于系统评价的且对各种备选干预方式进行利弊评估后 提出的最优指导意见）并遵循最新国际指南开发组织所颁布的指南制定步骤和相 关评价标准确定了本指南的评价标准，旨在以循证医学思想为指导，注重中医药特色，对既往相关证据进行充分收集和评价。其次，在本指南制定过程中，技术 内容主要遵循以下原则：a.针对证据分级的方法，总体思想认为来自多个随机 临床试验的系统综述或单个高质量的随机对照临床试验的证据等级最高，观察性研究证据等级较低。b.针对推荐强度，主要基于 GRADE 内容进行推荐，同时提 出在证据缺如或不能满足临床实际需求时，以专家共识推荐为主。c.专家共识是中医临床诊疗指南形成推荐意见的重要依据，基于此，本指南在起草过程中专家共识的形成主要基于改良的德尔菲法。d.本指南在实施前，除了需要对指南 制定质量使用

AGREEII 工具进行评价外，还从指南的实施条件是否满足，是否符合实际医疗工作需要等方面进行了指南适用性与合规性预评价。e.按照国际指南报告标准 RIGHT 进行报告，推向国际。f.制定计划按照目前国际上发布的指南更新报告规范，在未来 2-3 年进行更新。

2 指南制定技术路线

参考不同的国际临床实践指南制定组织有关临床实践指南制定过程和程序，结合世界中医药学会联合会国际组织标准发布的相关规定，本指南制定过程见图 2。

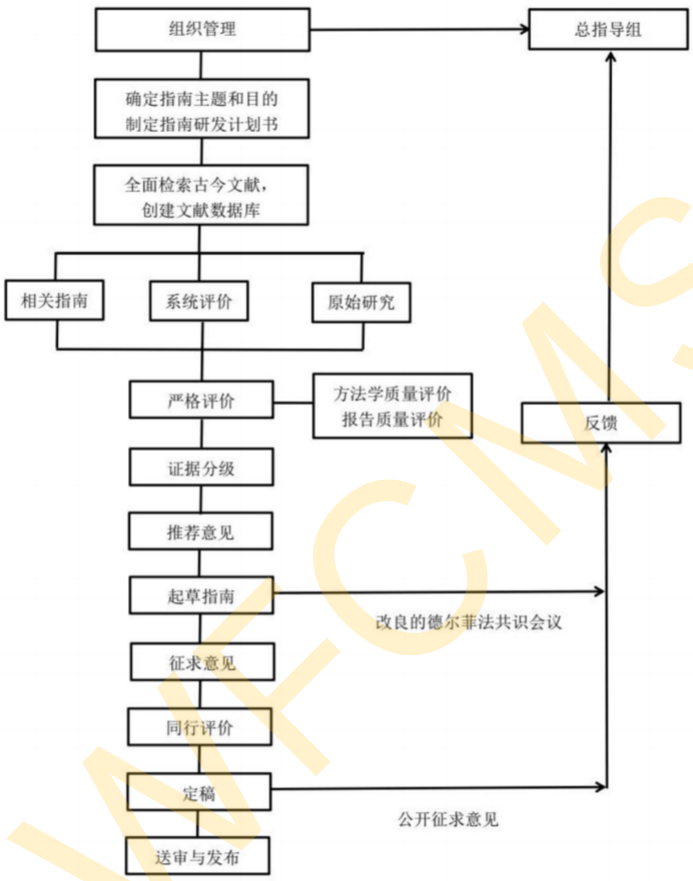

图 2 指南制定过程

3 总体内容

本指南正文共设 7 部分，主要技术内容包括:第 1-3 部分明确了本指南的范围、规范性引用文件和术语定义;第 4-6 部分明确了诊断、辨证和中医药治疗；第 7 部分明确了本指南附录和参考文献。

本指南以中医药辨证论治为主，最大限度地将循证结果和专家共识相结合，将具有一定优势特色的中医药干预措施应用到睑板腺功能障碍的诊疗中。因此，在参照并实施本指南前，医师需掌握一定的中医药知识，在诊疗过程中应密切关注患者的各项指标变化。另外，由于受到使用者地域、民族、种族等因素的影响，具体诊疗过程应依照实际情况而

定。

4 与相关法律、法规、强制性标准和临床实践指南的关系

本指南所推荐的相关治疗药物，均遵循国家最新《国家基本医疗保险、工伤保险和生育保险药品目录》、《国家基本药物目录》和《中国药典》所记载的内容。

四、重大分歧意见的处理经过和依据

本指南在制定过程中，未出现重大分歧意见。

五、其他应说明的事项、

无。

International Clinical Practice Guideline of Chinese Medicine

Meibomian Gland Dysfunction

International Organization Standard Formulation Explanations

I. General Working Information

Leading Drafting Institutions: The First Affiliated Hospital of Hunan University of Chinese Medicine; Ophthalmology Hospital, China Academy of Chinese Medical Sciences; The Affiliated Hospital of Shandong University of Traditional Chinese Medicine; Affiliated Eye Hospital of Shandong University of Traditional Chinese Medicine.

Participating Drafting Institutions: Ophthalmology Hospital, China Academy of Chinese Medical Sciences; The Affiliated Hospital of Shandong University of Traditional Chinese Medicine; Affiliated Eye Hospital of Shandong University of Traditional Chinese Medicine; Affiliated People's Hospital of Fujian University of Traditional Chinese Medicine; Chengdu Huashu Eye Hospital; Shanxi Eye Hospital; Chengdu University of Traditional Chinese Medicine Eye Academy/Affiliated Yinhai Eye Hospital; The Third Affiliated Hospital of Beijing University of Chinese Medicine; Tongren Hospital, Shanghai Jiao Tong University School of Medicine; China–Japan Friendship Hospital; Xi'an Hospital of Traditional Chinese Medicine; Affiliated Hospital of Tianjin University of Traditional Chinese Medicine; China Academy of Chinese Medical Sciences; Longhua Hospital, Shanghai University of Traditional Chinese Medicine; Beijing Tongren Hospital, Capital Medical University; Shuguang Hospital, Shanghai University of Traditional Chinese Medicine; Guangdong Provincial Hospital of Chinese Medicine; The Second Affiliated Hospital of Guangzhou University of Chinese Medicine; The First Affiliated Hospital of Guangxi University of Chinese Medicine; The Second Affiliated Hospital of Liaoning University of Traditional Chinese Medicine; The First Affiliated Hospital of Heilongjiang University of Chinese Medicine; The First People's Hospital Affiliated to Shanghai Jiao Tong University; Dongzhimen

Hospital, Beijing University of Chinese Medicine; Hebei Eye Hospital; Henan Provincial Hospital of Chinese Medicine; Hubei Provincial Hospital of Chinese Medicine; The Second Affiliated Hospital of Guizhou University of Traditional Chinese Medicine; Dongfang Hospital, Beijing University of Chinese Medicine; Shandong University of Traditional Chinese Medicine; Taiwan China Medical University Hsinchu Hospital; The University of Hong Kong; Hong Kong Soo Swee Ping Chinese Medicine Clinic; Wellspring Clinic, Vancouver BC, Canada; Singapore Chung Hwa Medical Institution; NEI/NIH, USA; American Learning and Vision Association, USA; Acupuncture and Health Care Association, USA; St. Olav Eye Clinic, Norway; Japan–China Health Science Association.

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II. Brief Introduction to the Standard Drafting Process

(e.g., when it was initiated, how the investigation was conducted, how opinions from various stakeholders were solicited, what review meetings were held, and the deliberation or voting status of the Standard Review Committee)

1. Guideline Development Principles

(e.g., when it was initiated, how the investigation was conducted, how opinions from various stakeholders were solicited, what review meetings were held, and the deliberation or voting status of the Standard Review Committee)

1. Guideline Development Principles

The International Clinical Practice Guideline of Traditional Chinese Medicine for Meibomian Gland Dysfunction was developed following the principles of "evidence-based, consensus-oriented, and experience-informed." The procedures, methods, and structure of guideline development drew upon internationally accepted methodologies for clinical practice guidelines, ensuring both scientific rigor and the distinctive characteristics of traditional Chinese medicine (TCM) clinical practice. The entire development process was based on evidence retrieval and extensive expert consultation, with in-depth discussions and analyses at each level. All processes and steps are traceable, ensuring evidence-based accountability.

2. Main Working Process

2.1 Initiation and Deployment Phase

2. Main Working Process

2.1 Initiation and Deployment Phase

This document was filed with and applied to the World Federation of Chinese Medicine Societies (WFCMS), after which the guideline title and specific content were determined. Currently, the International Clinical Practice Guideline of Traditional Chinese Medicine for Meibomian Gland Dysfunction has been approved by the WFCMS (Project No.: SCMNP2025-200).

2.2 Drafting Phase

2.2.1 Establishment of the Guideline Drafting Group

The project team members were determined by the principal investigator through telephone and information communication with experts in relevant professional fields.

2.2.2 Organizational Management

A WeChat working group was established for the development of this document, composed mainly of consensus experts and working group members.

Considering the need for timeliness, daily work was conducted primarily through online meetings and telephone communication. Regular internal discussion meetings and online exchange meetings were held, with records and archives maintained for each meeting.

2.2.3 Conflict of Interest Avoidance

All members participating in the development work have declared that no conflicts of interest exist. No explicit commercial, professional, or other interests related to the subject of this document, nor any conflicts of interest that could be affected by the outcomes of this document, were identified.

2.3 Determination of Topic and Scope

Guideline Title: International Clinical Practice Guideline of Traditional Chinese Medicine for Meibomian Gland Dysfunction.

Scope: This document specifies the TCM terminology and definitions, diagnosis, pattern differentiation, and treatment of meibomian gland dysfunction. This document serves as a reference for TCM ophthalmology practitioners in the diagnosis and treatment of meibomian gland dysfunction; physicians practicing integrated Chinese and Western medicine, Western ophthalmology, and other disciplines of TCM may also refer to the relevant content of this document.

2.4 Construction of Guideline Questions

2.4.1 Expert Interviews

2.4.1.1 Process and Methods for Determining the Interview Protocol

The interviewees were clinical experts with extensive practical experience, whose primary research direction is TCM treatment of meibomian gland dysfunction. These expert interviews were conducted in the form of online meetings, with a total of five interviewed experts as required by the standard. The interview outline was drafted under the guidance of the chief drafting group experts and completed by the drafting group members.

2.4.1.2 List of Interviewed Experts

Listed in tabular form. See Table 1.

Name	Institution	Title	Specialty
Bi Hongsheng	Affiliated Eye Hospital of Shandong University of	Professor	Integrated Chinese and Western Ophthalmology

	Traditional Chinese Medicine		
Xie Like	Ophthalmology Hospital, China Academy of Chinese Medical Sciences	Professor	TCM Ophthalmology
Hao Xiaofeng	Ophthalmology Hospital, China Academy of Chinese Medical Sciences	Professor	TCM Ophthalmology
Yan Jiachao	The First Affiliated Hospital of Hunan University of Chinese Medicine	Associate Professor	TCM Ophthalmology
Liu Guanghui	The First Affiliated Hospital of Fujian University of Traditional Chinese Medicine	Professor	TCM Ophthalmology

2.4.1.3 Interview Outline

Basic questions for the International Clinical Practice Guideline of Traditional Chinese Medicine for Meibomian Gland Dysfunction:

Definition-related — What is the definition of meibomian gland dysfunction?

Clinical questions for the Intervention Protocol for Meibomian Gland Dysfunction:

Diagnosis-related — What are the diagnosis and pattern differentiation of meibomian gland dysfunction?

Treatment-related — What are the TCM treatments for meibomian gland dysfunction? What are the distinctive external TCM therapies?

2.4.1.4 Interview Conclusions

Through the interviews, basic and clinical questions were preliminarily determined, clarifying the scope and definition of meibomian gland dysfunction as basic questions, as well as relevant clinical questions regarding diagnosis and treatment. The experts recognized the advantages of TCM intervention modalities for meibomian gland dysfunction.

Name	Interview Content
Bi Hongsheng	Meibomian gland dysfunction has a three-layer definition; currently, there is a lack of applicable diagnostic criteria, and relevant guideline standards should be referenced for diagnosis.
Xie Like	The concept of TCM treatment differs from that of Western medicine; the treatment of meibomian gland dysfunction should emphasize pattern differentiation and treatment. The diagnostic content may overlap to some extent with existing expert consensus and guidelines, and this protocol should focus on innovation.
Hao Xiaofeng	Treatment inadvertently brings anxiety to society; individualized treatment should be demonstrated.
Yan Jiachao	In various regions, there is a noticeable trend of various products claiming to be TCM-based; it is highly anticipated that the TCM guideline can be refined to specify which method is suitable for which stage.
Liu Guanghui	TCM external therapies have advantages in the treatment of meibomian gland dysfunction; standardization should be addressed.

2.5 Determination of Retrieval Strategy Using the PICO Principle

The retrieval strategy was divided into electronic retrieval and manual retrieval. Electronic retrieval of Chinese databases included CNKI, VIP, SinoMed, and WanFang Data; English databases included Medline, The Cochrane Library, Embase, and ClinicalTrials.gov. Manual retrieval mainly included diagnostic and treatment guidelines, standards, norms, drug instructions, patent specifications, relevant Chinese and Western ophthalmology textbooks and monographs, as well as unpublished research reports, dissertations, conference papers, and other grey literature. The retrieval period covered from database inception to January 2025. Chinese search terms included: meibomian gland dysfunction, dry eye syndrome, white astringent eye (Bai Se Zheng), traditional Chinese medicine, Chinese herbal medicine, Chinese patent medicine, etc. English search terms

included: Meibomian gland dysfunction, dry eye, white astringent, traditional Chinese medicine, Chinese herbal medicine, Chinese patent medicine, etc.

2.6 Evidence Screening and Data Extraction

After completing the literature retrieval, two researchers independently conducted preliminary screening by reading titles and abstracts, followed by rescreening based on the full texts of the initially screened studies. In case of disagreement, resolution was sought through discussion or consultation with a third party.

Evidence aimed at studying interventions to alleviate the occurrence and progression of meibomian gland dysfunction was included. Included study types comprised: randomized controlled trials, cohort studies, cross-sectional studies, guidelines, or expert consensus. Any indicator reflecting the alleviation of the occurrence and progression of meibomian gland dysfunction could be included as an outcome measure. Conference abstracts for which full texts could not be obtained were excluded.

2.7 Review of Existing Evidence

Through the above retrieval strategy, five relevant guidelines were identified, namely: the 2013 Expert Consensus on Clinical Diagnosis and Treatment of Dry Eye by the Corneal Disease Group of the Chinese Ophthalmological Society (2013); the Chinese Expert Consensus on Diagnosis and Treatment of Meibomian Gland Dysfunction (2017); the Chinese Expert Consensus on Meibomian Gland Dysfunction: Definition and Classification (2023); the Chinese Expert Consensus on Meibomian Gland Dysfunction: Diagnosis and Treatment (2023); and the Chinese Expert Consensus on Clinical Diagnosis and Treatment of Dry Eye (2024). In addition, the working group systematically reviewed the Chinese patent medicines and decoctions for treating meibomian gland dysfunction recorded in the National Basic Medical Insurance, Work-related Injury Insurance, and Maternity Insurance Drug Directory (2017 Edition), the National Essential Medicines List (2012 Edition) (Ministry of Health Order No. 93), and the Pharmacopoeia of the People's Republic of China (2015 Edition). Relevant

ancient texts on TCM treatment of this disease, as well as textbooks and physicians' works, were also reviewed for relevant information extraction.

2.8 Development of New Systematic Reviews

Inclusion criteria: a. The literature explicitly mentions "meibomian gland dysfunction," "dry eye syndrome," or "white astringent eye (Bai Se Zheng)"; b. Interventions: Chinese patent medicines, decoctions, acupuncture, or herbal fumigation and washing; c. Control measures: conventional Western medicine treatment (meibomian gland massage, artificial tears, anti-inflammatory agents, etc.); d. Primary outcome measures: meibomian gland function, BUT, etc.; secondary outcome measures: TCM syndrome scores, etc.; e. Study design types: all clinical studies, without limitation, with priority given to randomized controlled trials. Exclusion criteria: Duplicate publications; erroneous statistical methods; full text unavailable.

Through the above retrieval strategy, a total of 959 articles were obtained. The retrieved records were entered into NoteExpress 3.5 literature management software for deduplication, and preliminary screening was conducted from the records and abstracts. After obtaining the full texts of eligible literature, further screening was performed, ultimately yielding 110 articles. The literature screening process is shown in Figure 1.

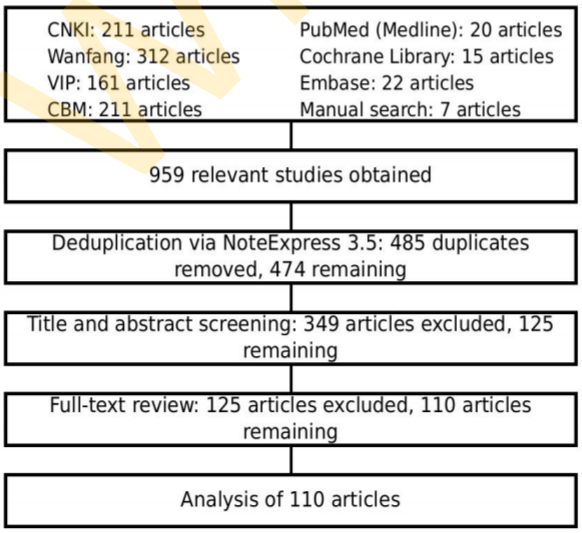

Figure 1 Literature Screening Process

2.9 Quality Appraisal of the Body of Evidence

2.9.1 Consensus Process Through Two Rounds of Modified Delphi Method

A modified Delphi method was used for questionnaire surveys, combined with expert online meetings to reach consensus on the content of this guideline. The selected consensus expert members were frontline clinical experts related to meibomian gland dysfunction, including both Chinese and Western medicine physicians, with a focus on TCM and integrated Chinese and Western ophthalmologists. Geographic distribution of experts was also considered, covering nine experts from five provinces and cities across China. The questionnaire survey period was from October 10, 2024, to December 10, 2024. The two rounds of questionnaires primarily evaluated disease diagnosis (incidence, clinical manifestations, ocular examination, special examinations), differential diagnosis, TCM pattern types, and all treatment measures based on evidence evaluation (formulas, Chinese patent medicines, auricular acupressure, acupuncture). After two rounds of the modified Delphi method and extensive solicitation of opinions, consensus was basically reached on all content of this guideline. The principles for determining the strength of recommendations were: if the number of strong recommendations for a treatment measure exceeded 75% of the total number of participants, it was strongly recommended; if the proportion of participants not recommending it was ≥50%, it was not recommended; all other situations were classified as weak recommendations.

2.9.2 Evidence Compilation and Archiving

The specific operational processes and resulting baseline materials for evidence retrieval, screening, and evaluation in this guideline were compiled and archived.

2.10 Consultation Phase

2.10.1 Questionnaire Consultation

During the development of this guideline, two rounds of expert meetings and two rounds of expert questionnaires were conducted. For the feedback from each round of meetings and questionnaires, working group members maintained detailed records, conducted in-depth discussions in conjunction with expert

opinions, and made revisions accordingly.

2.10.2 Consultation on the WFCMS Website

This guideline was published on the WFCMS website for public consultation.

2.10.3 Consultation at the Expert Review Meeting

The working group leader reported to the experts on the development status and relevant content of this guideline, as well as key issues for discussion. After the meeting, the working group summarized the expert opinions and made revisions.

2.3.4 Consultation with Overseas Experts

This guideline also solicited opinions from overseas experts.

III. Introduction to Main Technical Content

(e.g., technical indicators, parameters, formulas, performance requirements, test methods, inspection rules, and their basis—including tests and statistical data. For revised standards, a comparison between the new and old standards should be added.)

1. Basis for Guideline Development

The development of this guideline is based on the Institute of Medicine (IOM) 2011 definition of clinical practice guidelines (optimal guidance recommendations based on systematic reviews and benefit–risk assessments of various alternative interventions). It follows the latest guideline development steps and relevant evaluation criteria issued by international guideline development organizations to determine the evaluation standards for this guideline, aiming to be guided by evidence-based medicine thinking, emphasize TCM characteristics, and fully collect and evaluate existing relevant evidence. Furthermore, during the development of this guideline, the technical content primarily adheres to the following principles: a. Regarding evidence grading methods, the overall concept holds that evidence from systematic reviews of multiple randomized clinical trials or a single high-quality randomized controlled trial is of the highest grade, while evidence from observational studies is of lower grade. b. Regarding recommendation strength, it is primarily based on the GRADE (Grading of Recommendations Assessment, Development and Evaluation)

content for recommendations, while also proposing that when evidence is lacking or insufficient to meet clinical practical needs, expert consensus recommendations should be the main basis. c. Expert consensus is an important basis for forming recommendations in TCM clinical diagnosis and treatment guidelines; based on this, the formation of expert consensus in this guideline primarily relies on the modified Delphi method. d. Before implementation of this guideline, in addition to evaluating guideline development quality using the AGREE II (Appraisal of Guidelines for Research and Evaluation II) tool, a pre-evaluation of guideline applicability and compliance was also conducted from aspects such as whether implementation conditions are met and whether it conforms to actual medical work needs. e. Reporting follows the international guideline reporting standard RIGHT (Reporting Items for Practice Guidelines in Healthcare) to promote international dissemination. f. An update plan was formulated in accordance with currently internationally published guideline update reporting standards, with updates scheduled within 2–3 years.

2. Guideline Development Technical Route

Referencing the processes and procedures for clinical practice guideline development from various international clinical practice guideline development organizations, and combining them with the relevant regulations for the release of international organization standards by the World Federation of Chinese Medicine Societies, the development process of this guideline is shown in Figure 2.

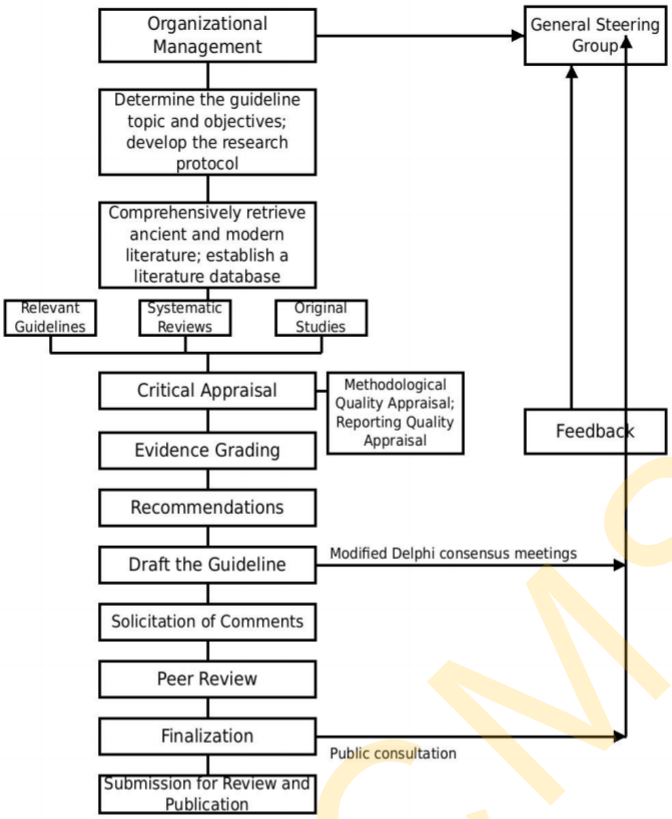

Figure 2 Guideline Development Process

3. General Content

The main text of this guideline comprises seven sections. The main technical content includes: Sections 1–3 define the scope, normative references, and terminology and definitions of this guideline; Sections 4–6 define diagnosis, pattern differentiation, and TCM treatment; Section 7 defines the appendices and references of this guideline.

This guideline focuses primarily on TCM pattern differentiation and treatment, maximizing the integration of evidence-based results and expert consensus, and applying TCM intervention measures with certain advantages and characteristics to the diagnosis and treatment of meibomian gland dysfunction. Therefore, before referring to and implementing this guideline, physicians need to possess certain TCM knowledge and closely monitor changes in patients' various

indicators during the diagnosis and treatment process. Additionally, due to the influence of factors such as the user's region, ethnicity, and race, the specific diagnosis and treatment process should be determined according to actual circumstances.

4. Relationship with Relevant Laws, Regulations, Mandatory Standards, and Clinical Practice Guidelines

The relevant therapeutic drugs recommended in this guideline all comply with the latest editions of the National Basic Medical Insurance, Work-related Injury Insurance, and Maternity Insurance Drug Directory, the National Essential Medicines List, and the Pharmacopoeia of the People's Republic of China.

IV. Handling and Basis for Major Divergent Opinions

No major divergent opinions arose during the development of this guideline.

V. Other Matters That Should Be Explained

None.