

## JAMA Dermatology | Consensus Statement

# Low-Dose Oral Minoxidil Initiation for Patients With Hair Loss

## An International Modified Delphi Consensus Statement

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**IMPORTANCE** The results of small studies suggest that off-label use of low-dose oral minoxidil (LDOM) may be safe and effective for patients with hair loss, but larger trials and standardized guidelines are lacking.

**OBJECTIVE** To create an expert consensus statement for LDOM prescribing for patients with hair loss.

**EVIDENCE REVIEW** The current literature on the pharmacological properties, adverse effect profile, and use of LDOM for patients with hair loss was reviewed. Topics of interest were identified, and a modified Delphi consensus process was created. A total of 43 hair loss specialist dermatologists from 12 countries participated in a modified Delphi process. Consensus was reached if at least 70% agreed or strongly agreed on a 5-point Likert scale.

**FINDINGS** Over 4 survey rounds, 180 items in the first round, 121 items in the second round, 16 items in the third round, and 11 items in the fourth round were considered and revised. A total of 76 items achieved consensus including diagnoses for which LDOM may provide direct or supportive benefit, indications for LDOM compared to topical minoxidil, dosing for adults (18 years and older) and adolescents (aged 12 to 17 years), contraindications, precautions, baseline evaluation, monitoring, adjunctive therapy, and specialty consultation. Pediatric use and dosing items for children younger than 12 years, and LDOM titration protocols fell short of consensus.

**CONCLUSIONS AND RELEVANCE** This international expert consensus statement regarding the off-label prescribing of LDOM for patients with hair loss can help guide clinical practice until more data emerge. Hair loss experts with experience treating pediatric patients were underrepresented on this expert panel. Future research should investigate best practices for LDOM use in pediatric patients. Other critical topics for further investigation include the comparative efficacy of topical minoxidil vs oral minoxidil, the safety of oral minoxidil for patients with a history of allergic contact dermatitis to topical minoxidil, the long-term safety of LDOM, and the use of other off-label forms of minoxidil, such as compounded formulations of oral minoxidil and sublingual minoxidil. As additional evidence-based data emerge, these recommendations should be updated.

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**H**air loss significantly impacts patients' quality of life, and it may be nonscarring or scarring. Etiologically, hair loss may be hereditary (androgenetic alopecia [AGA]); related to age; congenital (hair shaft disorders); traction induced; inflammatory (primary scarring alopecia); autoimmune (alopecia areata); or secondary to medical, surgical, or emotional stressors (telogen effluvium), infection (tinea capitis), and certain medications including cancer therapies.<sup>1</sup>

Topical minoxidil is approved by the US Food and Drug Administration (FDA) as an over-the-counter drug designed to treat male patients with AGA (minoxidil, 5% solution, or minoxidil, 5% foam, twice daily) and female patients with AGA (minoxidil, 2% solution, twice daily, or minoxidil, 5% foam, once daily).<sup>2,3</sup> It is also frequently prescribed off-label for other types of hair loss in children and adults.<sup>2-6</sup> Common adverse effects include transient shedding with initiation, hypertrichosis, and contact dermatitis, most commonly secondary to nonactive formulary ingredients, such as propylene glycol.<sup>2</sup>

Minoxidil, a potent peripheral vasodilator, was originally approved by the FDA in 1979 as an oral agent for patients with severe refractory hypertension with antihypertensive dosing ranging from 10 mg to 40 mg daily.<sup>6,7</sup> Interestingly, a significant adverse effect of oral minoxidil was hypertrichosis, leading to the development of topical minoxidil as a hair growth agent in the 1980s.

Minoxidil exerts its effects via various proposed pathways: (1) a vasodilator acting on adenosine triphosphate-sensitive potassium channels, (2) an anti-inflammatory agent, (3) inducer of the Wnt/ $\beta$ -catenin signaling pathway, (3) a 5- $\alpha$  reductase inhibitor and antiandrogen, and (4) an anagen extender.<sup>6</sup> Topical minoxidil is converted into its active form, minoxidil sulfate, via sulfotransferase enzyme activity in the outer root sheath of hair follicles, and oral minoxidil is absorbed in the gastrointestinal tract and converted to its activated sulfated form in the liver.<sup>6</sup> The systemic absorption of topical minoxidil is negligible, well below the minimum level of 20.0 ng per millimeter, at which hemodynamic changes in blood pressure have been documented.<sup>2</sup> Oral minoxidil reaches peak levels in plasma within an hour, has a half-life of 3 to 4 hours, and is excreted by the kidneys within 12 to 20 hours.<sup>6</sup>

Oral minoxidil is not a first-line antihypertensive agent due to the risk for fluid retention, tachycardia, and other potential adverse effects, such as pericardial and pleural effusion, cardiac tamponade, and angina pectoris, with antihypertensive dosing.<sup>7</sup> However, a growing number of research groups have reported on the off-label use of low-dose oral minoxidil (LDOM), ranging from 0.25 mg to 5 mg daily, as a safe and effective treatment option for male and female patients with AGA, age-related patterned thinning, traction alopecia, alopecia areata, telogen effluvium, scarring, and other forms of hair loss,<sup>4,5,8-22</sup> though some serious adverse effects have been reported.<sup>23,24</sup> This correlates with an increased demand for LDOM prescriptions in recent years.<sup>16</sup> As the current data on LDOM initiation and monitoring for hair loss are limited, there is a pressing need for an expert consensus-based statement for common use to maximize hair growth and minimize cardiovascular and other adverse effects.

## Methods

### Delphi Survey Design

The Delphi technique is an iterative process that collates anonymous expert opinions and provides controlled feedback over mul-

## Key Points

**Question** What are the best practice recommendations for off-label use of low-dose oral minoxidil (LDOM) for patients with hair loss?

**Findings** A total of 43 hair loss specialist dermatologists from 12 countries participated in a modified Delphi exercise and reached consensus on 76 items, including diagnoses for which LDOM may provide benefit, indications for when LDOM is preferred to topical minoxidil, adult and adolescent use, contraindications, precautions, baseline evaluation, monitoring, adjunctive therapy, and specialty consultation.

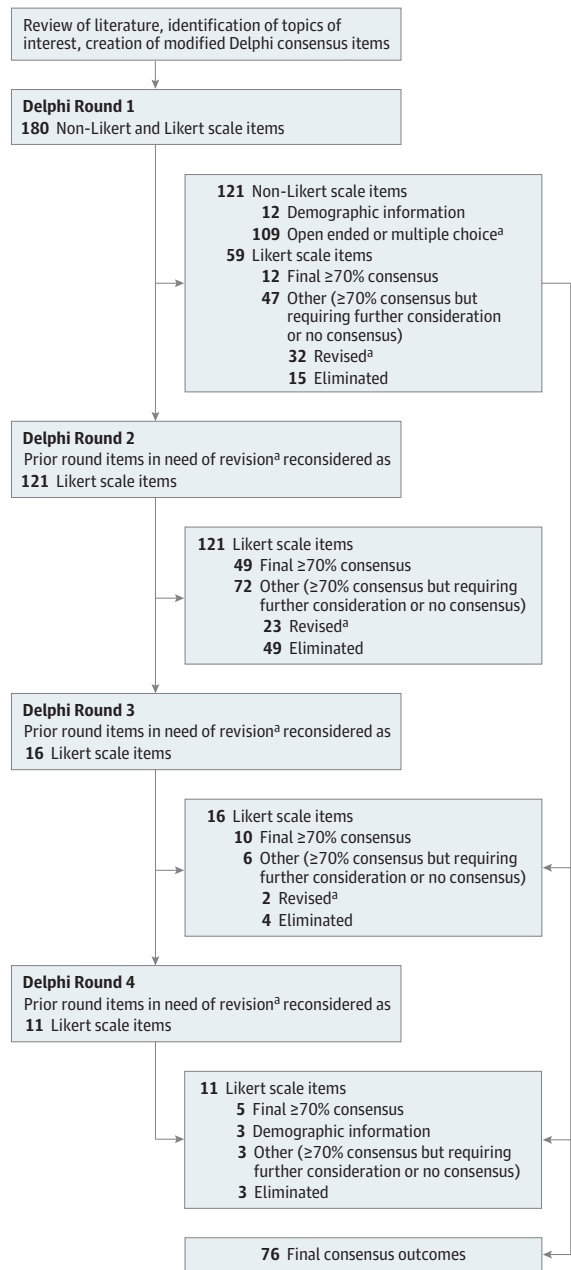
**Meaning** LDOM is an increasingly popular off-label treatment for patients with hair loss; this international expert consensus statement on LDOM use for patients with hair loss can help inform clinical practice until high-quality evidence-based data emerge.

iple rounds to generate structured and unbiased consensus on topics of interest.<sup>25</sup> For this study, the current literature on the pharmacological properties, adverse effect profile, and use of LDOM for patients with hair loss was reviewed, topics of interest identified, and a modified Delphi consensus process created by the multidisciplinary Low-Dose Oral Minoxidil Initiation (LOMI) steering committee (hair loss/dermatology experts, J.M.F., P.M., I.R.; medical dermatology expert, T.B.; pediatric dermatology expert, E.M.; cardiology expert, A.A.; University of California, San Francisco [UCSF], Department of Dermatology summer research fellow and study coordinator, Y.M.A.). This study adhered to the Standards for Quality Improvement Reporting Excellence (SQUIRE) reporting guideline (Figure).<sup>26</sup> Survey distribution, from March 21, 2023, to January 22, 2024, and secure data storage were managed with the UCSF's Research Electronic Data Capture (REDCap) platform.<sup>27</sup> This study was exempted from review by the University of California, San Francisco institutional review board.

Dermatologists with hair loss expertise, identified by clinical experience, research activities, and participation in recognized professional societies, including the North American Hair Research Society, International Federation of Hair Research Societies, and World Congress for Hair Research, were invited via email to join the LOMI expert panel and engage in multiple survey rounds addressing LDOM safety, efficacy, dosing, and monitoring for treating patients with hair loss. Experts were encouraged to answer items based on their clinical expertise and experience with LDOM; relevant literature was provided for review. To minimize bias, individual expert responses were anonymous from all except the study coordinator (Y.M.A.). Based on consensus parameters set by prior Delphi studies, consensus for a LOMI item was defined as at least 70% of experts indicating agree or strongly agree on a 5-point Likert scale.<sup>28-34</sup>

The initial survey round included items that were non-Likert scale (demographic, open-ended, or multiple choice), as well as items requiring a Likert scale response (strongly disagree, disagree, neutral, agree, strongly agree; Figure). After each round, aggregated responses were reviewed by the multidisciplinary LOMI steering committee, and feedback was provided to the LOMI expert panel. When indicated, survey items were revised for clarification or to incorporate expert comments and submitted for expert review in subsequent rounds. In rounds 2, 3, and 4, survey items were calibrated

**Figure. Low-Dose Oral Minoxidil Initiation Modified Delphi Consensus Process**



<sup>a</sup>Items that needed revision were reconsidered in subsequent rounds as single, multiple, and sometimes combined items.

to elicit Likert-only responses on items close to consensus. For rounds 2 and 3, close to consensus was defined as 60% to 69% of experts indicating agree or strongly agree on a 5-point Likert scale. For round 4, close to consensus was defined more stringently as 65% to 69% of experts indicating agree or strongly agree. Items achieving Likert scale consensus and not requiring further consideration were finalized and not reconsidered in subsequent rounds. Items that achieved at least 70% consensus but required further consider-

**Table 1. Hair Loss Expert Panel Demographics**

Variable	No. (%)	
	Round 1	Rounds 2-4
Experts invited, No. <sup>a</sup>	73	44
Experts participated, No.	44	43
Countries represented, No. <sup>b</sup>	12	12
Postresidency dermatology experience, median (IQR), y	14.5 (10.3-27.5)	15 (11-29)
Experience with LDOM, median (IQR), y	5 (3-6)	5 (3-6)
Patient care setting <sup>c</sup>		
Academic institution	34 (77.3)	33 (76.7)
Private practice	20 (45.5)	20 (46.5)
Hospital-based specialty group	7 (15.9)	7 (16.2)
Public service	5 (11.4)	5 (11.6)
Managed care organization	1 (2.3)	1 (2.3)
Patient population treated <sup>c</sup>		
Adults (≥18 y)	43 (97.7)	42 (97.6)
Adolescents (12-17 y)	24 (54.5)	24 (55.8)
Pediatric (<12 y)	17 (38.6)	17 (39.5)

Abbreviation: LDOM, low-dose oral minoxidil.

<sup>a</sup> Experts who fully completed the survey from the subsequent round were invited for the following rounds.

<sup>b</sup> Countries represented included Australia, Brazil, Canada, Georgia, Ireland, Italy, Poland, Spain, Thailand, Ukraine, the UK, and the US.

<sup>c</sup> Experts were able to indicate multiple patient care settings and/or populations treated.

ation, or did not achieve at least 70% consensus, were either revised or reconsidered in subsequent rounds or eliminated.

## Results

### Demographics of Expert Panel

Of 73 invited hair loss experts, 44 completed round 1 (Table 1). A total of 43 experts (98%), representing 12 countries, went on to complete rounds 2 through 4 of the modified Delphi process. LOMI experts who participated in all 4 rounds indicated a median (IQR) of 15 (11-29) years of postresidency dermatology experience and a median (IQR) of 5 (3-6) years of experience prescribing LDOM for patients with hair loss. Patient care settings were diverse, with many experts practicing in multiple settings, including 33 clinicians (76.7%) in academic institutions, 20 clinicians (46.5%) in private practice, 7 clinicians (16.2%) in hospital-based specialty groups, 5 clinicians (11.6%) in public service settings, and 1 clinician (2.3%) at a managed care organization. Forty-two clinicians (97.6%) reported treating adults with hair loss (defined as individuals 18 years and older); 24 clinicians (55.8%) reported treating adolescents with hair loss (defined as individuals aged between 12 and 17 years); and 17 clinicians (39.5%) reported treating pediatric patients with hair loss (defined as individuals younger than 12 years).

### Delphi Survey Rounds

LOMI experts considered items throughout 4 rounds: the first round included 180 non-Likert scale and Likert scale items; the second round, 121 Likert scale items; the third round, 16 Likert scale items; and the fourth round, 11 Likert scale items (Figure). A total of 76 items

**Table 2. Consensus Outcomes Regarding Who to Treat**

Item	Consensus reached, No. of experts (%)	Round No.
Patient populations for whom LDOM may be considered		
Adult (≥18 y)	40 (93.0)	2
Adolescent (12 to 17 y)	37 (86.0)	2
Indications		
Conditions for which LDOM may provide direct benefit		
AGA	42 (97.7)	2
Age-related patterned thinning	42 (97.7)	2
Alopecia areata	35 (81.4)	2
Telogen effluvium	37 (86.0)	2
Traction alopecia	34 (79.1)	2
Persistent chemotherapy-induced alopecia	36 (83.7)	2
Endocrine therapy-induced alopecia	36 (83.7)	2
Conditions for which LDOM may provide supportive benefit		
Lichen planopilaris	38 (88.4)	2
Frontal fibrosing alopecia	38 (88.4)	2
Central centrifugal alopecia	37 (86.0)	2
Fibrosing alopecia in a patterned distribution	34 (79.1)	2
Cases when LDOM may be considered over topical minoxidil		
Topical minoxidil is more expensive	31 (70.5)	1
Topical minoxidil application is time-consuming or logistically challenging	41 (93.2)	1
Topical minoxidil application results in undesirable product residue, hair texture change, or hair styling issues	42 (95.5)	1
Topical minoxidil may exacerbate an inflammatory process of the scalp (eg, cicatricial alopecia or primary cutaneous dermatitis, such as seborrheic dermatitis, eczema, or psoriasis)	41 (93.2)	1
Topical minoxidil has not been effective or has plateaued in efficacy	40 (90.9)	1
Enhanced hypertrichosis is a desired effect (eg, transgender patient population)	38 (86.4)	1
Contraindications for the use of LDOM		
Ongoing other drug therapy with significant oral minoxidil interaction	38 (86.4)	1
History of pericardial effusion/tamponade	36 (81.8)	1
History of pericarditis	32 (72.7)	1
Congestive heart failure	34 (79.1)	2
History of pulmonary hypertension associated with mitral stenosis	33 (76.7)	2
Pheochromocytoma	32 (74.4)	3
Patients who are pregnant or breastfeeding	42 (95.5)	1
Precautions for the use of LDOM		
History of tachycardia or other arrhythmia	36 (81.8)	1
Hypotension (blood pressure <90/60 mm Hg)	34 (77.3)	1
Kidney function impairment	38 (88.4)	2
Patients undergoing dialysis	38 (88.4)	2

Abbreviations: AGA, androgenetic alopecia; LDOM, low-dose oral minoxidil.

<sup>a</sup> Items for which contraindication consensus was achieved were excluded from precaution consideration.

achieved final consensus, including diagnoses for which LDOM may provide direct or supportive benefit, indications for LDOM compared to topical minoxidil, adult and adolescent dosing, contraindications, precautions, baseline evaluation, monitoring, adjunctive

therapy, and specialty consultation. Consensus was not achieved on pediatric use and dosing or LDOM titration protocols (eTable in the [Supplement](#)).

## Consensus Outcomes Regarding Who to Treat

### Patient Populations

Consensus was reached in round 2 that LDOM treatment may be considered for adult and adolescent patients (40 [93.0%] and 37 [86.0%] experts agreed, respectively; [Table 2](#)). Whether LDOM may be considered for pediatric patients fell short of consensus in round 2 (ie, only 23 experts concurred [53.5%]; eTable in the [Supplement](#)).

### Indications for LDOM Use

Strong consensus was reached that LDOM may provide direct benefit for AGA and age-related patterned thinning (42 [97.7%] and 42 [97.7%] experts agreed, respectively; [Table 2](#)). LOMI experts also concurred during round 2 that LDOM might provide direct benefit for other conditions in which follicular miniaturization or hair cycle disruption may be present, including 35 experts (81.4%) agreeing for alopecia areata, 37 experts (86.0%) for telogen effluvium, 34 experts (79.1%) for traction alopecia, 36 experts (83.7%) for persistent chemotherapy-induced alopecia, and 36 experts (83.7%) for endocrine therapy-induced alopecia. Consensus during round 2 was reached that LDOM may provide supportive benefit for the following forms of cicatricial alopecia: lichen planopilaris (38 experts [88.4%] agreed); frontal fibrosing alopecia (38 experts [88.4%] agreed); central centrifugal alopecia (37 [86.0%] agreed), and fibrosing alopecia in a patterned distribution (34 [79.1%] experts agreed). Diagnoses that did not reach consensus for either direct or supportive benefits from LDOM are detailed in the eTable in the [Supplement](#).

### Choice of LDOM vs Topical Minoxidil

Consensus was reached during round 1 that LDOM may be favored over topical minoxidil when LDOM is less expensive (31 experts [70.5%] agreed); is more convenient (41 experts [93.2%] agreed); topical minoxidil causes styling issues, undesirable product residue, or hair texture change (42 experts [95.5%] agreed); when topical minoxidil coincides with scalp inflammation (whether secondary to cicatricial alopecia or a primary cutaneous dermatitis, such as seborrheic dermatitis, eczema, or psoriasis; 41 experts [93.2%] agreed); topical minoxidil results in an ineffective or plateaued response (40 experts [90.9%] agreed), or the desire for enhanced hypertrichosis (eg, transgender patient population) are relevant to the patient (38 [86.4%] experts agreed; [Table 2](#)).

### Contraindications and Precautions

Consensus was achieved during rounds 1, 2, and 3 that the following should be considered contraindications for LDOM use: ongoing alternate drug therapy interacting significantly with oral minoxidil (38 experts [86.4%] agreed); history of pericardial effusion/tamponade (36 experts [81.8%] agreed); history of pericarditis (32 experts [72.7%] agreed); congestive heart failure (34 experts [79.1%] agreed); history of pulmonary hypertension associated with mitral stenosis (33 experts [76.7%] agreed); pheochromocytoma (32 experts [74.4%] agreed); and pregnancy or breastfeeding (42 experts [95.5%] agreed; [Table 2](#)).



LOMI experts reached consensus during rounds 1 and 2 that the following should be considered precautions for LDOM use: history of tachycardia or other arrhythmia (36 experts [81.8%] agreed); hypotension indicated by blood pressure level less than 90/60 mm Hg (34 experts [77.3%] agreed); kidney function impairment (38 experts [88.4%] agreed); and patients undergoing dialysis (38 experts [88.4%] agreed; Table 2).

Of note, items for which contraindication consensus was achieved were excluded from precaution considerations. Items that failed to reach consensus as either contraindications or precautions are detailed in the eTable in the Supplement. Consensus was reached on 2 items regarding minoxidil hypersensitivity in round 1, including the following: (1) "LDOM may be considered over topical minoxidil when topical minoxidil application results in skin irritation or allergy" and (2) "The following should be considered a contraindication for the use of LDOM: hypersensitivity to minoxidil" (43 [97.7%] and 39 [88.6%] experts agreed, respectively; eAppendix in the Supplement). However, on subsequent review, these statements were deemed vague regarding the type of allergy or hypersensitivity and route of administration of minoxidil and therefore were not included as final consensus outcomes.

### Consensus Outcomes Regarding How to Treat

#### Specialty Consultation Before Prescribing LDOM

LOMI experts concurred during round 2 that specialty consultation with primary care or cardiology clinicians may be sought before prescribing LDOM (41 experts [95.3%] agreed), especially when potential precautions or contraindications are identified (39 [90.7%] and 42 [97.7%] experts agreed, respectively), or coordination of care is needed (41 experts [95.3%] agreed, respectively; Table 3).

#### Baseline Testing Before Prescribing LDOM

Consensus was reached during round 2 that, in the absence of precautions, baseline laboratory and electrocardiogram evaluation results are not routinely indicated (39 [90.7%] and 40 [93.0%] experts agreed, respectively; Table 3). In the presence of relevant precautions, baseline laboratory and electrocardiogram evaluation may be considered in consultation with a specialist (32 [74.4%] and 37 [86.0%] experts agreed, respectively).

#### LDOM Dosing Considerations

Consensus was achieved during round 2 that the following patient characteristics may inform the determination of starting dosing of LDOM: sex (33 experts [76.7%] concurred), age (for adults, 35 experts [81.4%] concurred; for adolescents, 36 experts concurred [83.7%]), hypertrichosis as either an undesirable or desirable effect (40 experts concurred [93.0%]), and the risk for systemic adverse effects (42 experts concurred [97.7%]; Table 3). Additionally, the severity of baseline hair loss was considered an important factor for determining the maximum dosages of LDOM during round 2 (32 experts [74.4%] concurred).

LOMI experts were asked about their typical dosing practices in round 1; these open-ended responses facilitated the creation of Likert scale items reintroduced in round 3 (Table 3). The most frequently prescribed LDOM starting doses and dosing ranges achieved consensus during rounds 3 and 4 for female adults (starting dose, 1.25 mg daily, and dosing range, 0.625 mg to 5 mg daily, based on concurrence of 32 [74.4%] and 36 [83.7%] experts, respectively);

Table 3. Consensus Outcomes Regarding How to Treat

Item	Consensus reached, No. of experts (%)	Round No.
<b>Specialty consultation</b>		
When indicated a specialist from primary care or cardiology may be consulted before prescribing LDOM	41 (95.3)	2
Cases when a specialist may be consulted before prescribing LDOM		
A potential precaution is identified	39 (90.7)	2
A potential contraindication is identified	42 (97.7)	2
Coordination of care is indicated	41 (95.3)	2
<b>Baseline testing</b>		
In the absence of precautions, baseline laboratory testing (eg, complete blood count, metabolic panel) is not routinely indicated before LDOM initiation	39 (90.7)	2
If a precaution is identified before LDOM initiation, baseline laboratory testing (eg, complete blood count, metabolic panel) may be considered in consultation with a specialist	32 (74.4)	2
In the absence of precautions, a baseline electrocardiogram is not routinely indicated before LDOM initiation	40 (93.0)	2
If a potential cardiac precaution is identified before LDOM initiation, a baseline electrocardiogram may be considered in consultation with a specialist	37 (86.0)	2
<b>Dosing considerations</b>		
Patient characteristics that should be considered when determining the starting dose of LDOM		
Sex	33 (76.7)	2
Age		
Adult (≥18 y)	35 (81.4)	2
Adolescent (12-17 y)	36 (83.7)	2
Hypertrichosis (as either an undesirable or desirable effect)	40 (93.0)	2
Risk for systemic adverse effects	42 (97.7)	2
Patient characteristics that should be considered when determining the maximum dose of LDOM		
Sex	35 (81.4)	3
Adolescent age (12-17 y)	31 (72.1)	2
Severity of baseline hair loss	32 (74.4)	2
Hypertrichosis (as either an undesirable or desirable effect)	41 (95.3)	2
Risk for systemic adverse effects	41 (95.3)	2
Most frequently prescribed LDOM starting doses and dosing ranges by patient population		
Female adult		
Starting dose, 1.25 mg daily	32 (74.4)	3
Dosing range, 0.625-5 mg daily	36 (83.3)	3
Male adult		
Starting dose, 2.5 mg daily	32 (74.4)	4
Dosing range, 1.25-5 mg daily	39 (90.7)	3
Female adolescent		
Starting dose, 0.625 mg daily	35 (81.4)	3
Dosing range, 0.625-2.5 mg daily	33 (76.7)	3
Male adolescent		
Starting dose, 1.25 mg daily	33 (76.7)	3
Dosing range, 1.25-5 mg daily	33 (76.7)	3

(continued)

**Table 3. Consensus Outcomes Regarding How to Treat (continued)**

Item	Consensus reached, No. of experts (%)	Round No.
<b>Titration</b>		
Patients who are tolerating their current dose of LDOM in the absence of adverse effects can consult with the prescribing clinician about the risks and benefits of a dose increase	41 (95.3)	4
<b>Additional agents</b>		
Clinical situations when spironolactone may be coadministered with LDOM in biological female or transgender female patients		
Hirsutism	39 (90.7)	2
Acne	41 (95.3)	2
Polycystic ovary syndrome or other excess androgen syndrome	40 (93.0)	2
Lower extremity edema	35 (81.4)	2
Facial edema	31 (72.1)	2
β-Blockers may be coadministered with LDOM with specialty consultation	36 (83.7)	2

Abbreviation: LDOM, low-dose oral minoxidil.

<sup>a</sup> These dosing regimens reflect the Low-Dose Oral Minoxidil Initiation (LOMI) expert panel's most frequently used LDOM dosing practices. LOMI experts refrained from providing strict guidelines, specifically regarding upper dosing limits, emphasizing that dosing should be individualized based on patient history and response to therapy.

male adults (starting dose, 2.5 mg daily, and dosing range, 1.25 mg to 5 mg daily, based on concurrence of 32 [74.4%] and 39 [90.7%] experts, respectively); female adolescents (starting dose, 0.625 mg daily, and dosing range, 0.625 mg to 2.5 mg daily, based on concurrence of 35 [81.4%] and 33 [76.7%] experts, respectively); and male adolescents (starting dose, 1.25 mg daily, and dosing range, 1.25 mg to 5 mg daily, based on concurrence of 33 [76.7%] and 33 [76.7%] experts, respectively).

LOMI experts failed to achieve consensus during round 2 on whether LDOM may be considered for pediatric patients with hair loss (23 experts concurred [53.5%]). Pediatric dosing items asked of those experts who noted experience managing pediatric hair loss cases also failed to universally achieve consensus during round 3 (eAppendix and eTable in the [Supplement](#)).

Although specific titration protocols failed to reach consensus during round 2 (eAppendix in the [Supplement](#)), 41 LOMI experts (95.3%) concurred more generally during round 4 that patients tolerating their current dose of LDOM may discuss the risks and benefits of a dose increase with the treating clinician.

#### Additional Agents

Consensus was strong that spironolactone may be a useful adjunctive agent in biological female or transgender female patients with hirsutism; acne; or polycystic ovary syndrome (or another excess androgen syndrome) (39 experts [90.7%], 41 experts [95.3%], and 40 experts [93.0%] agreed, respectively). LOMI experts also noted during round 2 that spironolactone coadministration may be considered in biological female or transgender female patients when lower extremity edema or facial edema is present (35 [81.4%] and 31 [72.1%] experts agreed, respectively). Consensus was reached that, in the appropriate clinical context, β-blockers may be coadminis-

**Table 4. Consensus Outcomes Regarding How to Counsel Patients and Monitor Cases**

Item	Consensus, No. of experts (%)	Round No.
<b>Hair shedding and hypertrichosis</b>		
Patients may be counseled that the risk for transient hair shedding with LDOM initiation is likely to be about the same as with topical minoxidil initiation	32 (74.4)	2
Patients may be counseled that the risk for hypertrichosis with LDOM is likely to be more significant than with topical minoxidil initiation	34 (79.1)	2
<b>Monitoring</b>		
When a precaution has been identified, blood pressure monitoring may be recommended	39 (90.7)	2
<b>Cases when adverse effect monitoring may be recommended</b>		
When a precaution has been identified	42 (97.7)	2
With LDOM initiation	40 (93.0)	2
With LDOM dose escalation	41 (95.3)	2
<b>Adverse effects</b>		
Patients can be counseled to monitor for the sequelae of vasodilation: lightheadedness or dizziness and fast or abnormal heartbeat for at least 3-7 d	34 (79.1)	4
Patients can be counseled to monitor for the sequelae of salt and fluid retention (ie, swollen feet or legs, facial swelling, weight gain, chest pain, shortness of breath) for at least 4-6 wk	40 (93.0)	4
<b>Adverse effects that patients should also be instructed to monitor<sup>a</sup></b>		
Hypertrichosis	40 (100)	2
Headache	33 (82.5)	2
Signs of an allergic reaction	31 (77.5)	2
<b>Efficacy</b>		
The earliest time point at which LDOM should be expected to demonstrate efficacy is 3 mo	32 (74.4)	3
Patients who experience transient hair shedding with LDOM initiation may not note efficacy until 6 mo	36 (83.7)	4

Abbreviation: LDOM, low-dose oral minoxidil.

<sup>a</sup> These items were answered by 40 experts who earlier indicated that adverse effect monitoring was necessary in round 2. The percentages are reflected based on 40 experts' opinions.

tered with LDOM in consultation with a specialist (36 experts [83.7%] concurred; [Table 4](#)).

### Consensus Outcomes Regarding How to Counsel and Monitor

#### Hair Shedding and Hypertrichosis

Consensus was reached in round 2 that the risk for transient hair shedding with LDOM initiation is likely to be similar with topical minoxidil initiation (32 experts concurred [74.4%]), whereas, significant hypertrichosis is more probable with LDOM as compared with topical minoxidil use (24 experts concurred [79.1%]; [Table 4](#)).

#### Monitoring and Adverse Effects

Blood pressure monitoring may be recommended for patients for whom a precaution has been identified (39 experts [90.7%] concurred). Strong consensus was achieved in round 2 that adverse effect monitoring may be recommended in the following cases: when a precaution has been identified, with LDOM initiation, and with dose

escalation (42 [97.7%], 40 [93.0%], and 41 [95.3%] experts agreed, respectively).

Regarding adverse effects, LOMI experts concurred during round 4 that vasodilation secondary to oral minoxidil occurs acutely and depends on dose with peak effect occurring within 3 to 7 days. Patients can be counseled to monitor for sequelae including light-headedness, dizziness, and fast or abnormal heartbeat (34 experts [79.1%] concurred). They concurred during round 4 that salt and fluid retention secondary to oral minoxidil occurs subacutely/chronically, may be exacerbated by dietary salt intake, concurrent illness, and concomitant medications, and is most likely to present within 4 to 6 weeks. Patients can be counseled to monitor for salt and fluid retention sequelae including swollen feet or legs, facial swelling, weight gain, chest pain, and shortness of breath (40 experts [93.0%] concurred). LOMI experts who agreed that adverse event monitoring is needed (n = 40) reached consensus during round 2 that patients should be counseled to monitor for hypertrichosis when considered an undesirable effect (40 experts concurred [100%]); headache (33 experts concurred [82.5%]); and signs of an allergic reaction (31 [77.5%] experts concurred).

#### LDOM Efficacy

Consensus was reached in round 4 that the earliest time point at which LDOM should be expected to demonstrate efficacy is 3 months (32 experts concurred [74.4%]). In addition, patients who experience transient hair shedding with LDOM initiation may not note efficacy until 6 months after treatment initiation (36 experts concurred [83.7%]).

LDOM has become a commonly prescribed off-label alternative to topical minoxidil for treating patients with hair loss. This modified Delphi consensus statement involving 43 international hair loss specialists, with a 98% retention rate throughout the survey rounds, provided consensus findings on multiple aspects of LDOM use that may be useful for clinicians given the current lack of prospective data from studies with large sample sizes. These consensus findings addressed specific patient populations, indications, dosing, contraindications, precautions, baseline evaluation, specialty consultation, monitoring, adverse effects, and adjunctive therapy.

The initial survey round, which incorporated non-Likert and Likert scale items, was used to build subsequent rounds. After 4 rounds, 76 items achieved consensus with at least 70% of experts responding agree or strongly agree. It is worth highlighting that 27 of those items readily achieved at least 90% consensus after the first 2 rounds, suggesting broad agreement in practices among experts. The strongest agreement was reached regarding LDOM use in adults with AGA or age-related thinning and in situations when topical minoxidil may be ineffective or challenging. Additionally, strong agreement was reached on dosing considerations and contraindications for patients with potential systemic adverse effects, hypertrichosis, or for those who may be pregnant or nursing. Also, baseline blood pressure level measurement, electrocardiogram re-

sults, and specialty consultations were not recommended by at least 90% of experts when prescribing LDOM unless a precaution was identified. Topics that required more than 2 rounds to reach consensus included dosing ranges, titration, expected efficacy period, and the timeline of adverse events.

#### Limitations

Limitations of this study included the possibility that experts who were invited but did not participate in the consensus process may have differing opinions on LDOM use for patients with hair loss. Additionally, pediatric hair loss experts were underrepresented on the LOMI expert panel. The lack of consensus on pediatric use and dosing underscores the need for further research in the pediatric population. Furthermore, we did not include patient participation in our consensus process to level-set clinician practices.

The issue of whether oral minoxidil can be safely administered in patients who have true allergic contact dermatitis to topical minoxidil, excluding reactions to nonactive formulary ingredients, is of critical interest. However, the package insert for oral minoxidil does not explicitly address this, stating "minoxidil is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation."<sup>7</sup> This concern was not adequately resolved by this consensus process. However safe administration of LDOM has been reported in a case series of 9 patients who tolerated oral minoxidil despite a history of acute contact dermatitis attributed to topical minoxidil.<sup>35</sup> Until further data are available, a cautious approach can be considered, in which patients who develop cutaneous adverse effects with oral minoxidil should discontinue treatment.<sup>35</sup> Topics not addressed by this study but deserving future investigation include the comparative efficacy of topical vs oral minoxidil; the long-term safety of LDOM; and the use of other off-label forms of minoxidil, including compounded formulations of oral minoxidil and sublingual minoxidil, for patients with hair loss.

Considering the evolving landscape surrounding LDOM use, it is imperative to acknowledge that individualized patient needs and responses may vary, and clinicians should exercise their judgment in tailoring LDOM prescriptions and dosing accordingly. As we move forward, these guidelines should serve as a valuable reference but not an exhaustive standard. The authors encourage ongoing research and collaborative efforts to refine and update these recommendations in response to emerging evidence and clinical experience.

#### Conclusions

This consensus statement contributes substantially to the current understanding of LDOM prescribing for patients with hair loss, providing a solid foundation for clinical practice. These consensus recommendations serve as a crucial reference for dermatologists treating patients with hair loss, offering best-practice insights into LDOM prescribing until further data emerge.

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