

Micelle 60 at a glance

Care-organization review pack | Version 1.1 | Status checked October 1, 2026

Micelle 60 is a **hemp-derived CBD isolate softgel in development**, with a planned label amount of **60 mg CBD per softgel** and a planned bottle of **60 softgels**. It is intended for a possible organization-controlled pathway, not retail purchase or an individual medical recommendation. The separate 300 mg investigational program is not evidence for Micelle 60.

What can be reviewed today

A dated supplier-status register; a development product sheet with fields marked Pending; the primary-source CMS requirements crosswalk; an Example Quality Passport certificate and finished-product format model; an organization access framework, patient discussion guide, and briefing material. The Example certificate is synthetic, not a laboratory result.

What is still needed

Genuine isolate certificates, third-party finished-product potency and separate contaminant and microbial results, approved specifications and labels, manufacturing and insurance evidence, and organization-specific CMS election and plan approval remain pending. The planned per-container THC target alone proves neither compliance nor CMS eligibility. There is no represented product release or live supply service.

A useful briefing

A briefing can clarify the organization's questions, compare its own model responsibilities with Micelle's available material, list the documents needed for product qualification, and agree on next evidence requests. It is **not** an approval or procurement commitment. [Request an organization briefing or email the care-organization team](#). Do not send patient information.

Content is under review. See [current status and readiness](#) for dated changes. This collection is not a released-product dossier, CMS-approved plan, legal opinion, medical advice, insurance schedule or offer for retail sale.

Documents in this pack

Select a page reference to jump to that section. PDF bookmarks offer the same navigation. Each appended document keeps its original identification, version and issue date. The small pack page number at the lower right runs continuously across all sections.

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How to interpret status: Factual company information and dated source records are under review, not Example material. A prominent EXAMPLE watermark identifies sample measurements and planning templates. A source document’s own revision date may precede this pack’s October 1 assembly date.

CMS requirements and evidence status

Primary source: [CMS Substance Access Beneficiary Engagement Incentive](#). Checked October 1, 2026. This summary does not establish product eligibility. ACO REACH and EOM participants could begin offering the incentive April 1, 2026; eligible LEAD participants from January 1, 2027, subject in every case to their election, plan, CMS approval and model terms.

Participating model and election

Verified against CMS page, October 1, 2026

CMS requirement: Eligible ACO REACH and Enhancing Oncology Model (EOM) participants may begin offering the BEI April 1, 2026; it becomes available to eligible LEAD participants January 1, 2027. The participant must elect it for the applicable period.

Responsible party: Organization

Micelle status: Micelle provides product information for consideration, not model participation or CMS election.

CMS Implementation Plan

Planned approach

CMS requirement: A participant submits and maintains a plan naming product and dosing, distribution amount/frequency, beneficiary eligibility, safeguards and oversight; CMS approval is required.

Responsible party: Organization / CMS

Micelle status: Access framework and template structure available. No organization-specific plan or CMS approval is represented.

Product definition and law

Evidence pending

CMS requirement: CMS limits eligible products to federally legal hemp-derived products with no more than 0.3% delta-9 THC. It excludes inhalables; orally administered products above 3 mg tetrahydrocannabinols per serving (including delta-8, delta-10 and THCA); and products containing cannabinoids not naturally produced or capable of being produced by or in the cannabis plant during cultivation. State and local law also applies; CMS says its definition will adjust to legal changes.

Responsible party: Organization evaluates; supplier provides evidence

Micelle status: Planned isolate softgel and controlled testing structure. Final composition and genuine lot evidence pending; the planned <0.4 mg/container target alone proves neither compliance nor CMS eligibility.

Product quality and testing

Evidence pending

CMS requirement: Applicable production, quality and safety law; legally compliant source and high-quality farm. Third-party testing must measure cannabinoid potency accurately, separately from contaminant and microbial-hazard testing with negative results.

Responsible party: Organization procurement / supplier evidence

Micelle status: Ingredient evidence-status records A and B explain which source certificates are missing, and a blank finished-product certificate format model is available. Actual controlled certificates, independent finished-product results and laboratory engagement remain pending.

CMS requirements (continued)

Beneficiary and physician decision CMS requirement: Participant applies beneficiary criteria. A physician determines appropriateness and documents risks, benefits, goals, preferences, medication review and follow-up. Responsible party: Participating organization and affiliated physician Micelle status: Patient discussion guide available for review; no individual eligibility decision or medical advice on this website.	Planned approach
Procurement and direct supply CMS requirement: Participant controls procurement, contracting, storage, inventory and distribution; a qualified affiliated physician furnishes product directly. No retail receipt reimbursement. Responsible party: Participating organization Micelle status: Planned handling and lot-record model; no released supply service or contract terms are published.	Evidence pending
Cost and contracting CMS requirement: Up to \$500 per eligible beneficiary per year, subject to safeguards; Medicare does not pay for the product. No inducement or manufacturer selection remuneration; fair-market-value and referral restrictions apply. Responsible party: Participating organization Micelle status: No Micelle price, valuation method, coverage or contract is asserted. The \$500 limit is not a published Micelle price or a reimbursement claim.	Evidence pending
Reporting and integrity CMS requirement: Required quarterly reports, supplemental information on request, participant oversight and program-integrity safeguards. Responsible party: Participating organization Micelle status: Synthetic example CSV illustrates a possible de-identified record shape only. Not a CMS submission or approved reporting format.	Planned approach

Up to USD 500 per eligible beneficiary per year is the CMS participant’s furnishing ceiling, not a product price or Medicare reimbursement; Medicare does not pay participants for the products. CMS does not prescribe a public valuation method on this page. [Request a briefing](#) for an organization-specific review.

Micelle 60

Development product sheet | Version 1.0 | Status checked October 1, 2026

Micelle 60 is a hemp-derived CBD isolate softgel in development. The **planned** label amount is 60 mg CBD per softgel; the planned pack contains 60 softgels. It is not a released product, a clinical recommendation, a laboratory certificate or an assertion of CMS eligibility.

Product description

Field	Current statement or status
Form	Softgel in development; final formulation and excipient list Pending.
CBD source	Hemp-derived CBD isolate planned; genuine ingredient identity and purity certificates Pending.
Planned label amount	60 mg CBD per softgel; target, not a measured release result.
Planned pack	60 softgels per bottle; label artwork is a draft, not approved packaging.
Route	Planned oral softgel. No dosing regimen, clinical effect or condition-specific use established here.
Separate program	NW PharmaTech's 300 mg investigational product is different; no evidence or outcome is transferred to Micelle 60.

Fields requiring controlled specification and release evidence

Control area	Evidence required; current status
Identity and potency	Finished-product identity, CBD assay, units, acceptance range, method and batch record: Pending. Potency is measured against an approved specification; it is not expected to be "negative".
Total THC basis	Combined tetrahydrocannabinols per finished container, including THCA, methods and limits: Pending. A planned less-than-0.4 mg target alone proves neither compliance nor CMS eligibility.
Contaminants / microbes	Third-party contaminant and microbial panels, methods, detection limits and qualifying negative results: Pending. These are distinct from potency measurements.
Other controls	Other cannabinoids, residual solvents, pesticides, elemental impurities, stability, storage, shelf life, manufacturer and approved release criteria: Pending.
Traceability	Real lot identifiers, approved labels, finished-product certificate, notice process and change history: Pending. Current Quality Passport lot records are Example data only.

Content is under review. Read the [dated readiness register](#) and [product specification page](#) for current supporting records. For organization review, [request a briefing](#). Do not send patient information.

Supplier diligence status

Micelle 60 | Version 1.1 | Status checked October 1, 2026

This factual register distinguishes material available for review from missing evidence. It is not a certificate, released-product specification, manufacturing approval, insurance schedule or statement of CMS eligibility. Any linked Example lot values are synthetic.

Content is under review. See [the dated status and readiness register](#) for the latest record and next actions.

Entity, relationship and contact

NW Micelle Therapeutics, Inc. trades as Micelle Therapeutics and is described on the [About page](#) as part of the NW PharmaTech group. This pack does not include a corporate filing or infer intellectual-property ownership or manufacturing engagement from the group relationship. Organizational enquiries: team@nwpharmatech.com or +44 20 3693 3791 (UK number; service hours have not been verified). Correspondence: NW Micelle Therapeutics, Inc., c/o NW PharmaTech Ltd, Beaufort Gardens, Knightsbridge, London SW3 1PW, United Kingdom.

Product and evidence boundary

Micelle 60 is a hemp-derived CBD isolate softgel in development. The planned label amount is 60 mg CBD per softgel and 60 softgels per bottle. A planned target or Example lot record does not establish production specifications, legal compliance, product release, clinical suitability, or eligibility for the Substance Access Beneficiary Engagement Incentive. The separate NW PharmaTech 300 mg investigational programme is not evidence for this 60 mg product.

Evidence class	Current status	Boundary
Product description	Planned approach	Development-only label and formulation; final control records pending.
Ingredient certificates A/B	Pending evidence	Status records A and B identify missing source material; no laboratory values are asserted. Actual controlled isolate certificates have not been supplied.
Finished-product certificate	Pending evidence	Only a format model exists. No measured commercial lot or independent lab report.
Example lot certificates	Published Example	UI demonstration with synthetic values; not laboratory reports.
Manufacturing and insurance	Pending evidence	No verified manufacturing approval, production lot or coverage schedule published.

Data handling and accessibility: See the [Privacy Notice](#) and [accessibility page](#). Do not send patient information through the briefing route. Manual assistive-technology and Spanish professional reviews remain pending in the dated register.

Dated evidence register

Source: website readiness register, checked October 1, 2026. Functional owners identify accountable workstreams, not named approvals or completed reviews.

Product definition and planned specification

Published

Supporting record / gap: Product page, isolate-input specification structure and Label draft v1 are published. These are development documents, not final release specifications.

Functional owner: Product development | **Updated:** 2026-10-01

Next action: Confirm the controlled finished-product specification, manufacturer, storage conditions and shelf life before first release.

[Open current supporting page](#)

Scientific and legal interpretation

Pending evidence

Supporting record / gap: Federal primary sources are linked from the transition page. No completed independent scientific or legal review is recorded.

Functional owner: Scientific and legal functions | **Updated:** 2026-10-01

Next action: Obtain and record review of claim-bearing and condition-specific content before its publication.

[Open current supporting page](#)

Ingredient certificates

Pending evidence

Supporting record / gap: Two sanitized ingredient-evidence status records are available; actual controlled isolate certificates have not been supplied. Example lot PDFs are not laboratory certificates.

Functional owner: Quality function | **Updated:** 2026-10-01

Next action: Obtain verified source certificates and reconcile identities, methods, dates and acceptance limits.

[Open current supporting page](#)

Finished-product testing and laboratory

Pending evidence

Supporting record / gap: A finished-product certificate format model is published without measured laboratory results. No ISO/IEC 17025 laboratory engagement or released commercial lot is evidenced.

Functional owner: Quality function | **Updated:** 2026-10-01

Next action: Document laboratory engagement, validate methods and publish genuine released-lot reports when available.

[Open current supporting page](#)

Label, lot and traceability

In progress

Supporting record / gap: Label draft v1 and clearly marked Example A, B and C lot records show the proposed public traceability format only.

Functional owner: Product and quality functions | **Updated:** 2026-10-01

Next action: Approve production labels and reconcile actual lot identifiers, certificates, notices and correction history before release.

[Open current supporting page](#)

Organization implementation material

Published

Supporting record / gap: Access framework, planned five-stage workflow and organizational briefing materials are available. Publication is not implementation or CMS approval.

Functional owner: Organization partnerships | **Updated:** 2026-10-01

Next action: Work with each participating organization on its own model election, approved plan and controls.

[Open current supporting page](#)

Micelle model-participant election

Not applicable

Supporting record / gap: The CMS Substance Access incentive is elected by participating ACO REACH, EOM or LEAD organizations, not by a prospective product supplier. This does not exempt the product or participant from applicable requirements.

Functional owner: Organization partnerships | **Updated:** 2026-10-01

Next action: Each interested organization must assess eligibility, elect the incentive and obtain its own CMS-approved implementation plan.

[Open current supporting page](#)

Enquiry transmission

Pending evidence

Supporting record / gap: Email and telephone routes are visible. The website request form is disabled because controlled database and mail transport have not been tested in production.

Functional owner: Operations and privacy functions | **Updated:** 2026-10-01

Next action: Configure storage and delivery, test validation, errors, receipt and privacy handling before enabling web forms.

[Open current supporting page](#)

Product concerns and recall arrangements

In progress

Supporting record / gap: The public concern page provides telephone, correspondence and FDA MedWatch routes. A dedicated Micelle adverse-event owner, formal complaint processing and recall procedure are not evidenced.

Functional owner: Safety and quality functions | **Updated:** 2026-10-01

Next action: Document accountable intake, escalation, investigation and recall arrangements before product release.

[Open current supporting page](#)

Spanish language review

Pending evidence

Supporting record / gap: Structural Spanish pages exist; professional human translation review has not been documented.

Functional owner: Communications function | **Updated:** 2026-10-01

Next action: Complete and record professional language review before full Spanish publication.

[Open current supporting page](#)

Manual accessibility review

Pending evidence

Supporting record / gap: Automated accessibility, responsive and document checks have run; a documented manual assistive-technology review is not available.

Functional owner: Accessibility function | **Updated:** 2026-10-01

Next action: Complete keyboard and assistive-technology review and record remediations before first product release.

[Open current supporting page](#)

Insurance and commercial terms

Pending evidence

Supporting record / gap: No verified coverage schedule, policy limits, approved commercial terms or product price are available for publication.

Functional owner: Operations and commercial functions | **Updated:** 2026-10-01

Next action: Verify coverage and controlled price/contract records before publishing them.

[Open current supporting page](#)

Label draft v1

EXAMPLE PACKAGING ARTWORK. This is flat design artwork, not a physical product photograph and not approved packaging. The identifier is illustrative and the QR destination opens an Example lot record.

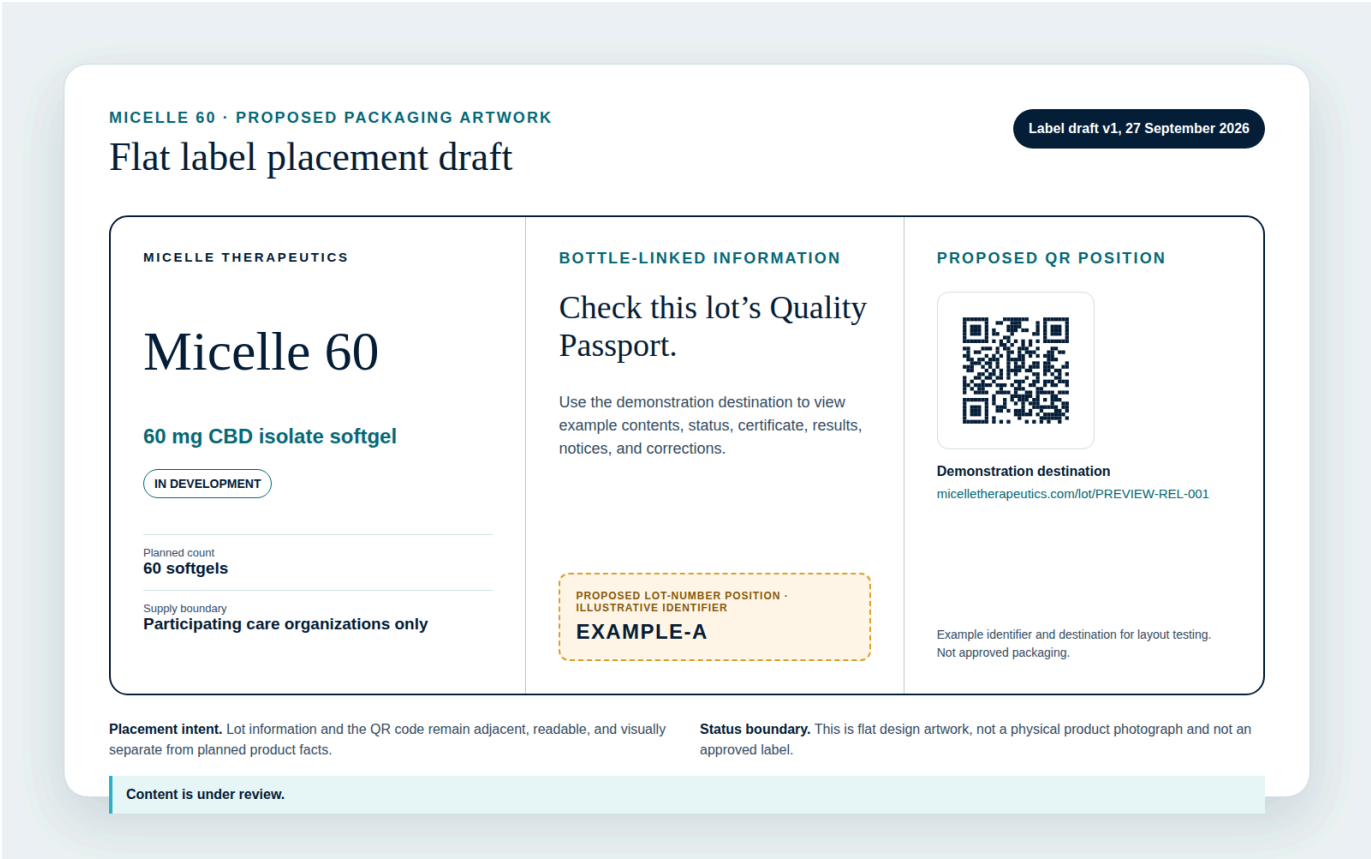


Figure 1: Micelle 60 flat label artwork showing proposed lot-number, lot-URL, and demonstration QR placement.

Sample material. The pictured lot identifier and QR route are for interface demonstration only.

Micelle 60 Example A certificate

EXAMPLE WITH SAMPLE DATA. This user-interface demonstration is not a laboratory report, does not describe a manufactured or released product, and must not be used for a supply or clinical decision.

Report ID
Sample report A-001

Product
Micelle 60

Lot and status
Example A, released example record

Version
2026-09-29

Key results

Analyte	Specification	Example result	Unit	Status
CBD per softgel	60 mg planned label amount	59.7	mg	Example pass
Total THC per container	Not more than 0.4 mg from December 11, 2026	Not detected	-	Example pass
Heavy metals	Within release specification	Pass	-	Example pass
Pesticides	Not detected above limits	Pass	-	Example pass
Residual solvents	Within release specification	Pass	-	Example pass
Microbials	Within release specification	Pass	-	Example pass

Sample material. Every value and status on this page is illustrative. The testing laboratory, methods, reporting limits, and release decision are not represented as real.

Record notes

No sample notice is in effect for Example A. A not-detected demonstration result does not guarantee a negative drug test.

- Every result in this document is sample data.
- A real released-lot certificate would identify the testing laboratory, approved method, specification, result, unit, reviewer, and issue date.
- Ingredient results are not finished-product results.
- Corrections would create a new version while preserving the superseded document in the public history.

Federal timing and evidence boundary

The limited Section 781 exclusions begin November 12, 2026. The broader finished-product restriction, including the more-than-0.4 mg combined-total-per-container threshold, begins December 11, 2026. This threshold does not by itself establish product compliance, approval, release, or CMS eligibility.

Primary sources: [Public Law 119-37 Section 781](#) and [Public Law 119-103 Section 2019](#).

Product boundary

Micelle 60 is in development, to be supplied only through participating care organizations. It is not offered for retail sale. This example makes no health claim and does not give individual medical advice.

EXAMPLE

Finished-product certificate format model

EXAMPLE FORMAT MODEL. NO LABORATORY RESULTS. This document defines fields for a future Micelle 60 finished-product certificate. It is not a certificate of analysis and does not represent a manufactured or released lot.

Document identity

Field	Required content
Product	Micelle 60
Lot	Printed lot identifier
Report ID	Laboratory-issued controlled identifier
Version and issue date	Current document version and issue date
Laboratory	Name and address supplied by the issuing laboratory
Authorization	Laboratory authorization and reviewer fields

Key-result fields

Analyte	Required reporting basis	Status
CBD per softgel	Result, unit, method, and specification	Pending real certificate
Total THC per container	Combined total, including THCA, with reporting basis	Pending real certificate
Other cannabinoid results	Result, unit, method, and reporting limit	Pending real certificate

Full-panel structure

Panel	Required fields
Identity and potency	Analyte, specification, result, unit, method, status
Related substances	Named analyte, reporting limit, result, unit, method, status
Residual solvents	Named solvent, result, unit, method, limit, status
Elemental impurities	Named element, result, unit, method, limit, status
Microbial quality	Named test, result, method, limit, status
Physical quality	Appearance, fill, integrity, water, and other controlled checks

Sample material. The table is a field model only. It does not supply specifications, laboratory values, testing dates, accreditation, review, approval, or release.

Document controls

- The current certificate must identify its version and issue date.
- A correction must preserve the prior version and explain what changed.
- The selected certificate must stay linked to the public lot record.
- Ingredient evidence must remain separate from finished-product evidence.

EXAMPLE

Publication and evidence boundary

A future certificate will be published only as issued from controlled source material for a specific finished-product lot. This format model does not fill missing values, name a laboratory, state accreditation, or convert another product’s results into Micelle 60 evidence.

Federal reporting context

The limited Section 781 exclusions begin November 12, 2026. The broader finished-product restriction, including the more-than-0.4 mg combined-total-per-container threshold, begins December 11, 2026. The threshold alone does not establish product compliance, approval, release, or CMS eligibility.

Primary sources: [Public Law 119-37 Section 781](#) and [Public Law 119-103 Section 2019](#).

Product boundary

Micelle 60 is in development, to be supplied only through participating care organizations. It is not offered for retail sale. This format model does not give individual medical advice.

EXAMPLE

Access framework for care organizations

EXAMPLE PLANNING MATERIAL. Micelle 60 is in development, to be supplied only through participating care organizations if released and approved. It is not offered for retail sale. Medicare pays \$0 for the product. This is not an executed program agreement, CMS approval or individual medical advice.

Requirement map

Domain	Organization responsibility	Micelle planning material
Governance	Assign clinical, quality, legal, privacy and operational decision rights.	Program overview and responsibility register.
Eligibility	Apply local criteria and record the physician decision.	Sample checklist for organization adaptation.
Shared decision	Record benefits, risks, goals, preferences, medicines and follow-up.	Sample discussion and follow-up structure.
Product qualification	Qualify the product and each released lot against controlled evidence.	Development product sheet and Quality Passport examples.
Supply traceability	Record receipt, storage, lot, quantity, supplying clinician and local identifier.	Sample supply-log fields.
Concerns and notices	Maintain local escalation, emergency and lot-linked communication procedures.	Public concern route and planned lot notices.
Quarterly reporting	Prepare the organization's required reports and supporting records.	Synthetic export structure without patient information.

Sample material. Each organization determines its own governance, legal, clinical, privacy, quality, safety, eligibility and reporting requirements.

Five planning stages

The stage titles, organization responsibilities and Micelle support below are sourced from the website's canonical workflow. These steps remain preparatory, not operational supply.

<p>01. Product review</p> <p>Organization: Evaluate the product definition, federal and state law, evidence and procurement suitability; keep the organization's own approval record.</p> <p>Micelle's planned support: Provide the development specification and source-linked Quality Passport examples, without claiming released-product compliance.</p>
<p>02. Organization implementation plan</p> <p>Organization: Elect the incentive if appropriate; prepare, submit and maintain a CMS-required plan covering product, eligibility, amount and frequency, safeguards, distribution and oversight. CMS approval belongs to CMS.</p> <p>Micelle's planned support: Offer an adaptable access framework and source-linked CMS crosswalk for the organization's review.</p>
<p>03. Shared decision-making</p> <p>Organization: An affiliated physician determines appropriateness, reviews medications and interactions, documents goals, preferences, risks and benefits, and plans follow-up.</p> <p>Micelle's planned support: Provide patient discussion materials, not an individual medical recommendation or eligibility decision.</p>
<p>04. Supply</p> <p>Organization: Arrange lawful procurement, inventory, storage and qualified-physician supply through the participant; do not direct beneficiaries to retail reimbursement.</p> <p>Micelle's planned support: If product is released, provide lot-labelled product and handling records under agreed arrangements; no supply service is live now.</p>
<p>05. Lot records and reporting</p> <p>Organization: Keep organization-controlled records and submit CMS-required quarterly reports; respond to requests and product notices. Do not place patient information in public examples.</p> <p>Micelle's planned support: Plan a public Quality Passport for each released lot and a checked de-identified export. The sample quarterly file is synthetic, not an actual CMS submission.</p>

Current material status

Framework, sample Quality Passport and briefing are available now for organization review; controlled product release, laboratory evidence and operational supply remain gated. The BEI is elected by an eligible participant organization, with a required CMS-approved implementation plan; the participant cannot direct beneficiaries to retail reimbursement.

Contact and sources

Request an [organization briefing](#) or email team@nwpharmatech.com. Do not include patient information. See the [CMS crosswalk](#) and [readiness register](#).

Prepare for your visit.

A short guide to help you have a clear conversation with your care team about Micelle 60.

01

Before your visit

- Write down every medicine and supplement you take.
- Note allergies, recent symptoms, and changes in your health.
- Bring the name of your care organization and the best way to contact you.
- Do not stop or change a medicine unless your care team tells you to.

02

Questions to ask

- What is the goal of adding Micelle 60 to my care plan?
- Could it interact with any medicine or supplement I take?
- What should I watch for, and who should I contact if I have a concern?
- How will my care team review whether the plan is still right for me?

03

What to record after the conversation

Plan

What you and your care team decided.

Follow-up

When the next review will happen.

Contact

Who to call with a health or product concern.

Micelle 60 status

In development · Not offered for retail sale

Micelle 60 is in development, to be supplied only through participating care organizations. It is not offered for retail sale. This guide does not give individual medical advice.

EXAMPLE · Version 1.1 · 29 September 2026

For product questions: team@nwpharmatech.com · micelletherapeutics.com

For urgent medical help, call 911. For questions about your own health, contact your care team.

Every bottle has a page.

Care-organization briefing

Micelle 60 | Version 1.2 | October 1, 2026

Sample material. This planning aid is not a released-product dossier, executed program agreement, CMS-approved implementation plan or individual medical advice. It uses synthetic Example reporting values. Micelle 60 remains a development-stage hemp-derived CBD isolate softgel; Medicare pays \$0 for the product.

Purpose and boundary

Use this briefing to compare organizational responsibilities with Micelle’s available development records and determine which evidence is still needed. It does not establish laboratory results, product qualification, supply readiness or CMS eligibility.

What is available today

- **Review Room:** product, quality, implementation, patient material and dated readiness topics.
- **Development product sheet and specification structure:** planned 60 mg CBD per softgel and 60-softgel bottle; controlled fields Pending.
- **Quality Passport:** Example A, B and C interface records, not commercial lots or laboratory certificates.
- **Readiness register:** dated functional-owner actions and unresolved evidence.

For a structured 30-minute discussion, [request a briefing](#) or [email the care-organization team](#). Do not include patient information.

EXAMPLE

Requirement map

Topic	Organization responsibility	Micelle planning material
Governance	Assign clinical, quality, legal, privacy and operational decision rights.	Responsibility register and access framework.
Eligibility	Determine local criteria, exclusions, physician decision and documentation.	Sample planning structure only.
Shared decision	Record risks, benefits, preferences, medication review and follow-up.	Patient discussion guide.
Product qualification	Qualify finished product against approved specifications and genuine lot evidence.	Development sheet, source-status register and Example Passport.
Supply traceability	Control ordering, receipt, storage, lot and qualified-physician furnishing.	Example supply-log fields; no live supply.
Concerns and notices	Maintain escalation, emergency and lot-linked notice procedures.	Public concern route and planned lot notices.
Quarterly reports	Submit CMS-required reports and maintain source records.	Synthetic de-identified CSV; not a CMS submission.

Sample material. An organization must determine its own clinical, quality, legal, privacy and safety controls. Publication of planning material is not implementation or CMS approval.

Five stages, one accountable pathway

These stage names and responsibilities use the same canonical record as the website and access framework. All supply statements are conditional.

<p>01. Product review</p> <p>Organization: Evaluate the product definition, federal and state law, evidence and procurement suitability; keep the organization's own approval record.</p> <p>Micelle's planned support: Provide the development specification and source-linked Quality Passport examples, without claiming released-product compliance.</p>
<p>02. Organization implementation plan</p> <p>Organization: Elect the incentive if appropriate; prepare, submit and maintain a CMS-required plan covering product, eligibility, amount and frequency, safeguards, distribution and oversight. CMS approval belongs to CMS.</p> <p>Micelle's planned support: Offer an adaptable access framework and source-linked CMS crosswalk for the organization's review.</p>
<p>03. Shared decision-making</p> <p>Organization: An affiliated physician determines appropriateness, reviews medications and interactions, documents goals, preferences, risks and benefits, and plans follow-up.</p> <p>Micelle's planned support: Provide patient discussion materials, not an individual medical recommendation or eligibility decision.</p>
<p>04. Supply</p> <p>Organization: Arrange lawful procurement, inventory, storage and qualified-physician supply through the participant; do not direct beneficiaries to retail reimbursement.</p> <p>Micelle's planned support: If product is released, provide lot-labelled product and handling records under agreed arrangements; no supply service is live now.</p>
<p>05. Lot records and reporting</p> <p>Organization: Keep organization-controlled records and submit CMS-required quarterly reports; respond to requests and product notices. Do not place patient information in public examples.</p> <p>Micelle's planned support: Plan a public Quality Passport for each released lot and a checked de-identified export. The sample quarterly file is synthetic, not an actual CMS submission.</p>

Physician and patient materials

Material	Purpose	Status
Development product sheet	Planned label, pack, formulation and Pending specification fields.	Published development document
Controlled specification	Approved identity, assay, limits, method, effective date and source record.	Pending
Quality Passport	Lot identity, status, selected certificate, values and notice history.	Example records only
Patient discussion guide	Questions for a visit, medicines, goals and follow-up.	Versioned PDF available
Shared-decision record	Organization-controlled risks, preferences, medication review and follow-up.	Organization-specific
Concern route	Product concerns, emergency boundary and correspondence.	Public route; formal processing pending
Quarterly export	Organization reporting without patient identifiers in public examples.	Synthetic CSV only

Product distinction

Micelle 60 is a hemp-derived CBD isolate softgel in development. The separate NW PharmaTech 300 mg investigational product has no clinical, pharmacokinetic, exposure, efficacy, safety or comparability bridge to Micelle 60.

Sample quarterly record shape

Sample material. Every value and identifier below is illustrative. It does not represent actual supply, participants, testing, notices, performance or a CMS-approved report format.

Field	Example value
Reporting period	Example: 2027 Q1
Organization code	Example: ORG-DEMO-001
Prepared date	Example: 15 April 2027
Export version	Example: 1.0
Patient information	Not included

Example lot	Units	Recipients	Notices	Record status
EXAMPLE-A	Example: 120	Example: 72	Example: 0	Example released state
EXAMPLE-B	Example: 24	Example: 18	Example: 1	Example withdrawn state
EXAMPLE-C	Example: 60	Example: 41	Example: 0	Example corrected state

Exception and privacy fields

A real organization-controlled report would reconcile lot counts, certificates, notices, concerns, exceptions and document version. Do not include patient names, dates of birth, medical-record numbers, free-text clinical notes or other identifiers in shared public material. [Download the synthetic example CSV.](#)

Next steps and contact

A briefing can confirm the organization’s review questions, the responsible functions, the documents already available and the product evidence still required. It is not a clinical, legal, CMS or procurement sign-off.

Resource	Direct link
Development product sheet	Open the current product specification page
Quality Passport	View Example lot records
CMS crosswalk	Review source-linked model requirements
Care-organization pathway	Review the five-stage workflow
Status and readiness	Read dated evidence gaps and owner actions
Arrange a briefing	Open the direct email and telephone options

Email the care-organization team at team@nwpharmatech.com. Do not include patient information. Recheck online status before relying on this dated planning document.

EXAMPLE