

## MEDICAID POLICY INFORMATION SHEET

**Policy Analyst:** Vicki Goethals

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Initial ☐

Public Comment ☒

Final ☐

### Brief description of policy:

This policy announces that certain Active Pharmaceutical Ingredients (API) and excipients will be covered on compound drug claims.

### Reason for policy (problem being addressed):

On July 13, 2011, the Centers for Medicare & Medicaid Services (CMS) issued a notice to states clarifying the coverage policy for APIs and excipients. The notice clarified that although APIs and excipients do not meet the definition of covered outpatient drugs as defined in section 1927(k)(2) of the Social Security Act, states may choose to cover certain APIs and excipients and receive federal matching funds if those products were noted as covered in their state plan. Therefore, certain API and excipient products will be added to the State Plan in order to become eligible for both federal matching funds and Medicaid coverage.

### Budget implication:

☒ budget neutral

☐ will cost MDHHS \$ , and (select one) budgeted in current appropriation

☐ will save MDHHS \$

### Is this policy change mandated per federal requirements?

No

### Does policy have operational implications on other parts of MDHHS?

No

### Does policy have operational implications on other departments?

No

### Summary of input:

☐ controversial

☒ acceptable to most/all groups

☐ limited public interest/comment

### Supporting Documentation:

State Plan Amendment Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Public Notice Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If Yes, please provide status:	If yes,
<input type="checkbox"/> Approved <input checked="" type="checkbox"/> Pending <input type="checkbox"/> Denied	Submission Date:
Date: Approval	Date:

<b>DRAFT FOR PUBLIC COMMENT</b>  <b>Michigan Department of Health and Human Services</b>		
	<b>Project Number:</b> 1933-Pharmacy	<b>Date:</b> December 16, 2019

**Comments Due:** January 21, 2020  
**Proposed Effective Date:** As Indicated  
**Direct Comments To:** Vicki Goethals  
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<b>Policy Subject:</b> Coverage of Active Pharmaceutical Ingredients and Excipients  <b>Affected Programs:</b> Medicaid, Healthy Michigan Plan, Children's Special Health Care Services (CSHCS)  <b>Distribution:</b> Pharmacy Providers, Federally Qualified Health Centers, Tribal Health Centers  <b>Summary:</b> This policy announces that certain Active Pharmaceutical Ingredients (APIs) and excipients will be covered on compound drug claims.  <b>Purpose:</b> Certain APIs and excipient products are eligible for both federal matching funds and Medicaid coverage. The purpose of this bulletin is to provide for coverage of those APIs and excipients for Medicaid Pharmacy Fee-for-Service (FFS) reimbursement, which will help ensure standards of care and patient compliance for compounded drug therapies.  <b>Cost Implications:</b> None  <b>Potential Hearings &amp; Appeal Issues:</b> None
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<b>State Plan Amendment Required:</b> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> If yes, date submitted:	<b>Public Notice Required:</b> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Submitted date:
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<b>Tribal Notification:</b> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> - <b>Date:</b> September 21, 2019
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<b>THIS SECTION COMPLETED BY RECEIVER</b>
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<input type="checkbox"/> <b>Approved</b>	<input type="checkbox"/> <b>No Comments</b>
<input type="checkbox"/> <b>Disapproved</b>	<input type="checkbox"/> <b>See Comments Below</b>
	<input type="checkbox"/> <b>See Comments in Text</b>

<b>Signature:</b>	<b>Phone Number</b>
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<b>Signature Printed:</b>
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<b>Bureau/Administration</b> <i>(please print)</i>	<b>Date</b>
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# Proposed Policy Draft

Michigan Department of Health and Human Services  
Medical Services Administration

**Distribution:** Pharmacy Providers, Federally Qualified Health Centers, Tribal Health Centers

**Issued:** February 1, 2020 (Proposed)

**Subject:** Coverage of Active Pharmaceutical Ingredients and Excipients

**Effective:** As Indicated (Proposed)

**Programs Affected:** Medicaid, Healthy Michigan Plan, Children's Special Health Care Services (CSHCS)

**NOTE: Implementation of this policy is contingent upon approval of a State Plan Amendment by the Centers for Medicare & Medicaid Services (CMS).**

The purpose of this bulletin is to provide for coverage of certain Active Pharmaceutical Ingredients (APIs) and excipients for Medicaid Pharmacy Fee-for-Service (FFS) reimbursement. Effective for dates of service on and after October 1, 2019, the APIs and excipients listed in the attached document will be covered on compound drug claims. The coverage of these products helps ensure standards of care and patient compliance for compounded drug therapies. The list of covered APIs and excipients will also be maintained on the Michigan Medicaid Pharmacy Benefits Manager website at [Michigan.magellanrx.com](https://michigan.magellanrx.com).

APIs are bulk drug substances, which are defined by the U.S. Food and Drug Administration (FDA) as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient of the drug product. An excipient is an inactive substance used in a compound that assists with medication delivery (e.g., mineral oil for topical applications, flavored syrup for liquid cough products, etc.).

## Active Pharmaceutical Ingredients

NDC	Description
38779245805	COENZYME Q-10 POWDER
38779245808	COENZYME Q-10 POWDER
38779245809	COENZYME Q-10 POWDER
51552048904	CREATINE MONOHYDRATE POWDER
51552048905	CREATINE MONOHYDRATE POWDER
51552048907	CREATINE MONOHYDRATE POWDER
51927257100	CREATINE MONOHYDRATE POWDER
51552066505	L-CITRULLINE POWDER
51552066507	L-CITRULLINE POWDER
51927261000	L-CITRULLINE POWDER
51552098807	L-ORNITHINE HCL POWDER
52372083401	L-ORNITHINE HCL POWDER
52372083402	L-ORNITHINE HCL POWDER
62991281001	L-ORNITHINE HCL POWDER
62991281002	L-ORNITHINE HCL POWDER
38779256400	PENDERM CREAM BASE
38779256401	PENDERM CREAM BASE
38779256405	PENDERM CREAM BASE
38779256407	PENDERM CREAM BASE
38779256408	PENDERM CREAM BASE
38779256409	PENDERM CREAM BASE
51927104800	PCCA BASE ANHYDROUS OINT
51927288300	BASE, PCCA POLYPEG WAX
51927329500	PCCA VANISHING BASE CREAM
51927336000	PCCA POLYGLYCOL TROCHE BASE
38779055103	SODIUM BENZOATE POWDER
51552022105	SODIUM BENZOATE POWDER
62991138101	SODIUM BENZOATE POWDER
62991138102	SODIUM BENZOATE POWDER
62991138104	SODIUM BENZOATE POWDER
00019739603	SODIUM BICARBONATE POWDER
00019739620	SODIUM BICARBONATE POWDER
00019741203	SODIUM BICARBONATE AR POWD

NDC	Description
00228157904	SODIUM BICARBONATE POWDER
00228157916	SODIUM BICARBONATE POWDER
00367157904	SODIUM BICARBONATE POWDER
00367157916	SODIUM BICARBONATE POWDER
00395268501	SODIUM BICARBONATE POWDER
00395268594	SODIUM BICARBONATE POWDER
00395571694	SODIUM BICARBONATE POWDER
00406739603	SODIUM BICARBONATE POWDER
00406739620	SODIUM BICARBONATE POWDER
00406741203	SODIUM BICARBONATE AR POWD
00923083004	SODIUM BICARBONATE POWDER
10106350601	SODIUM BICARBONATE POWDER
10106350605	SODIUM BICARBONATE POWDER
10106350607	SODIUM BICARBONATE POWDER
10106350805	SODIUM BICARBONATE POWDER
10106350901	SODIUM BICARBONATE POWDER
10106350905	SODIUM BICARBONATE POWDER
17317049701	SODIUM BICARBONATE POWDER
17317049705	SODIUM BICARBONATE POWDER
17317157001	SODIUM BICARBONATE POWDER
17317157005	SODIUM BICARBONATE POWDER
24385068694	SODIUM BICARBONATE POWDER
51552005905	SODIUM BICARBONATE POWDER
51552005906	SODIUM BICARBONATE POWDER
51552005907	SODIUM BICARBONATE POWDER
51552005909	SODIUM BICARBONATE POWDER
51552005916	SODIUM BICARBONATE POWDER
55532117016	SODIUM BICARBONATE POWDER
87701039633	BL SODIUM BICARBONATE POWD

## Excipients

NDC	Description
00574030216	ORA-SWEET-SF SYRUP
00574030316	ORA-PLUS SUSPENDING VEHICLE
00574030416	ORA-SWEET ORAL SYRUP
00574031116	ORA-BLEND SUSPENSION
00574031216	ORA-BLEND SF SUSPENSION
00904669716	BLENDED SUSPENDING COMPOUND
00904669816	ORAL SUSPENDING COMPOUND PLUS
00904669916	SWEETENING SUSPEND COMPOUND
09046069716	BLENDED SUSPENDING COMPOUND
09046069816	ORAL SUSPENDING COMPOUND PLUS
09046069916	SWEETENING SUSPEND COMPOUND