Final Federal Targeted Market Conduct Examination of
UnitedHealthcare Insurance Company, HIOS ID #98809
State of Texas as of October 29, 2024

Examination Report: 98809– 2021 – FED – 1

In accordance with Title 45 of the Code of Federal Regulations (C.F.R.), Section 150.313, the Center for Consumer Information and Insurance Oversight (CCIIO) has completed a targeted Market Conduct Examination (Examination) of UnitedHealthcare Insurance Company, HIOS ID #98809, (Issuer) in the State of Texas. The Examination review period was January 1, 2021 through September 30, 2021, and was called to assess the Issuer's compliance with section 2713(a) of the Public Health Service Act (PHS Act) and implementing regulations:

- Coverage of preventive health services – 45 C.F.R. § 147.130.

CCIIO also reviewed the Issuer's compliance with the following:

- Coverage of COVID-19 diagnostic testing – Families First Coronavirus Response Act, Pub. L. 116-127, div. F § 6001(a)(1) and (2).[1]

[1] References in this document to § 6001 of the Families First Coronavirus Response Act refer to that statute, as amended by § 3201 of division A of the Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116-136.

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I. Executive Summary

The Center for Consumer Information and Insurance Oversight (CCIIO) has conducted a targeted Market Conduct Examination (Examination) of UnitedHealthcare Insurance Company (Issuer) in Texas to assess the Issuer's compliance with the federal market reform requirements mandating coverage of certain preventive health services – section 2713 of the PHS Act and implementing 45 C.F.R. § 147.130, and coverage of COVID-19 diagnostic testing – Families First Coronavirus Response Act, Pub. L. 116-127, Div. F § 6001(a)(1) and (2). The period covered by the Examination was January 1, 2021 through September 30, 2021 (Examination Period).

A random sample of 1,576 Issuer-generated claims was selected and reviewed. An additional sample of 1,137 claims was selected (2,713 claims samples in total) to evaluate the Issuer's exceptions process for coverage of contraceptive services. This additional sample was selected by analyzing contraceptive pharmacy claims that were rejected for reason codes associated with medical management techniques, such as prior authorization and step therapy. In addition to the selected claim samples, 40 Issuer documents were reviewed (2,753 total claim files and documents).

CCIIO discovered one violation by the Issuer affecting two individuals for failing to provide coverage of preventive health services without cost sharing, and one violation by the Issuer affecting one individual for failing to provide coverage of COVID-19 diagnostic testing without cost sharing. Consistent with the findings detailed in this Examination report, within 90 calendar days for Finding one, and 60 calendar days for Finding two, from the date of receipt of this final report, the Issuer is directed to take corrective measures such as modifying policies and procedures to ensure future compliance, notifying members of the policy revisions, conducting a self-audit to identify any inappropriately denied claims, re-adjudicating those identified claims, and providing CCIIO with a list of claims identified and re-adjudicated.

CCIIO also noted one observation[2] in this Examination report regarding the transparency and expediency of the exceptions process for requesting a cost sharing waiver for contraceptive drugs and devices and regarding deference of the determination of the attending provider.

This report is by exception; the Examination Results section only indicates areas where findings were noted and includes responses from the Issuer to criticisms in this report (when provided). In summary, findings were identified for the following Federal requirements:

[2] Observations are concerns noted during the examination about Issuer conduct that does not violate a regulation or statute but is inconsistent with sub-regulatory guidance issued by the Departments of Labor, Health and Human Services, and Treasury (the Departments) that reflects the Departments' interpretation of legal requirements.

a. Coverage of preventive health services – section 2713(a) of the PHS Act and 45 C.F.R. § 147.130(a)(1); and,
b. Coverage of COVID-19 diagnostic testing – Families First Coronavirus Response Act, Pub. L. 116-127, div. F § 6001(a)(1) and (2).

The Examination identified practices that do not comply with applicable Federal requirements, some of which may also violate State insurance laws and regulations.

The Issuer is directed, within 90 calendar days for Finding one, and 60 calendar days for Finding two, from the date of receipt of this final report, to take immediate corrective action with respect to the findings identified in this report to demonstrate its ability and intention to conduct business in accordance with Federal requirements. When applicable, corrective actions for other jurisdictions and/or affiliates should also be addressed.

II. Scope of Examination

CCIIO conducted this Examination pursuant to 45 C.F.R. § 150.313. The Examination Period was January 1, 2021 through September 30, 2021. The purpose of the Examination was to assess the Issuer's compliance with select applicable Federal requirements.

This report identifies findings that have been discovered based on the review and sampling procedures identified in this report but does not constitute an exhaustive list of violations that may require correction. Some non-compliant practices may not have been discovered or noted in this report. Failure to identify or address business practices that do not comply with Federal requirements does not constitute acceptance of such practices.

The Examination and testing methodologies followed standards established by the National Association of Insurance Commissioners and procedures developed by CCIIO. All samples were selected by using a computer-generated, random sample program unless otherwise stated herein.

CCIIO organized the Examination's sample population by selecting preventive services recommended guidelines by the following: United State Preventive Services Task Force (USPSTF); Health Resources and Services Administration (HRSA), Women's Preventive Services Guidelines; and Pediatric Bright Futures and Immunizations. CCIIO then organized samples by the Issuer's insurance markets, as well as paid claims and denied claims. The methodology was designed so that claims included in one sample area would not be duplicated in other review areas.

Area Reviewed	Population	Sample Size
45 CFR 147.130(a)(1)(i)- USPSTF A & B Recommendations individual medical paid claims[3]	2,585	25
USPSTF A & B Recommendations individual denied medical claims	554	25
USPSTF A & B Recommendations group paid medical claims	731,792	183
USPSTF A & B Recommendations group denied medical claims	32,588	107

[3] We acknowledge that, since the completion of CMS's audit of UHIC of TX, the United States District Court for the Northern District of Texas issued a final judgment in Braidwood Management Inc. v. Becerra, No. 4:20-cv-00283-O (N.D. Tex. Mar. 30, 2023), which held, among other things, that the USPSTF's recommendations operating in conjunction with PHS Act section 2713(a)(1) violate the Appointments Clause. The government has appealed the final judgment, and in the meantime, the Fifth Circuit has granted the government's motion for a partial stay of the district court's order. See No. 23-10326 (5th Cir. May 15, 2023).

Area Reviewed	Population	Sample Size
45 C.F.R. § 147.130(a)(1)(iv)- HRSA Women's Preventive Services Guidelines individual paid medical claims	718	25
HRSA Women's Preventive Services Guidelines individual denied medical claims	72	25
HRSA Women's Preventive Services Guidelines group paid medical claims	108,790	366
HRSA Women's Preventive Services Guidelines group denied medical claims	8,553	216
45 C.F.R. § 147.130(a)(1)(ii) and (iii)-Pediatric Bright Futures and Immunizations individual paid medical claims	5,017	25
Pediatric Bright Futures and Immunizations individual denied medical claims	486	25
Pediatric Bright Futures and Immunizations group paid medical claims	794,471	183
Pediatric Bright Futures and Immunizations group denied medical claims	33,489	107
Pharmacy individual paid claims	4,057	25
Pharmacy individual denied claims	771	25
Pharmacy group paid claims	286,478	107
Pharmacy group denied claims	53,466	107
Pharmacy Women's Contraceptive - reject reason code 806 (step therapy) *	1,086	1,086
Pharmacy Women's Contraceptive - reject reason code 75 (prior authorization) *	51	51
Policy and procedure documents, claim processing documents, provider manuals, and other miscellaneous documents provided by the Issuer	N/A	40

*Note: CCIIO requested an additional sample to further analyze contraceptive pharmacy claims that were rejected for reason codes associated with medical management techniques, such as prior authorization and step therapy.

To test the effectiveness of the contraceptive formulary exception process, denied claims data was analyzed for denials related to Product Not Covered, Prior Authorization, and Step Therapy. Members with denials or claim handling with the following attributes were targeted for sampling:

1. Multiple rejected attempts to fill a contraceptive Rx, followed by a paid claim for a different contraceptive
2. Non-formulary contraceptive approved with no previous rejections
3. Multiple rejected attempts to fill a contraceptive Rx, followed by a paid claim for the same contraceptive
4. Multiple rejected attempts to fill a contraceptive Rx – not filled, no other contraceptives filled during the exam period.

The Issuer's responses to criticisms issued during the Examination process appear after the finding in the Examination Results section of this report.

III. Issuer Profile

UnitedHealthcare Insurance Company (UHIC), a Connecticut corporation. UHIC is licensed as a life, accident and health insurer in the Virgin Islands, District of Columbia, Commonwealth of the Northern Mariana Islands, American Samoa, Puerto Rico, Guam, and in all states except New York. UHIC is a direct wholly owned subsidiary of UHIC Holdings, Inc. (formerly known as Unimerica, Inc.), a Delaware general business corporation. UHIC Holdings, Inc. is a direct wholly owned subsidiary of United HealthCare Services, Inc. (UHS), a Minnesota general business corporation. UHS is a direct wholly owned subsidiary of UnitedHealth Group Incorporated (United), the ultimate parent in the insurance holding company system.

UnitedHealthcare Insurance Company is a licensed health insurer in the State of Texas.

IV. Summary of Findings

Finding 1	
Summary	Failing to cover preventive health services without cost sharing for evidence-based items or services, including immunization, and contraception. This occurred because of the Issuer's internal policy requiring that preventive diagnosis codes be paired with preventive service procedure codes for a service to be processed as preventive without cost sharing. The provider submitted claims for service codes 92650 (comprehensive check of a hearing aid in monaural context) and 87625 (infectious agent antigent detection – HPV), for preventive items and related services. However, the Issuer did not provide CCIIO with provider guidance requiring submission of these claims with specified coding pointers to ensure that these services are processed as preventive and without cost-sharing.
Citations	Section 2713 (a) of the PHS Act and 45 C.F.R. § 147.130(a)(1)
Corrective Action	**Corrective Actions:** Conduct a self-audit to identify all claims from January 1, 2021 through the date this final report is issued for service codes 92650 and 87625 for which coverage was denied or imposed cost sharing for preventive health services Within 90 calendar days from the date of this final report, provide documentation containing the results from the self-audit, re-adjudicate all such claims and provide a list of the claims identified and re-adjudicated to CCIIO. Include the claim number, date of service, date of original denial or imposition of cost sharing, date of re-adjudication, amount paid to provider, provider reimbursement check number issued, amount refunded to member, and member refund check number issued on the date of re-adjudication. Review and update claim policies to ensure compliance with Federal preventive health services statutes and rules. Provide the updated claim policies to CMS with 90 calendar days from the date of this final report.

Finding 2	
Summary	Failing to provide coverage of COVID-19 diagnostic testing without cost sharing. This occurred because of the Issuer's internal policy requiring that diagnosis codes be paired with certain service procedure codes for a service to be processed as COVID 19 diagnostic testing without member cost sharing. For Criticism 3, the Issuer agreed with this finding. When asked about the cost-sharing applied, the Issuer stated "Patient responsibility was applied in error. An adjustment will be done to issue additional payment to the provider and an updated PRA/EOB issued to reflect no patient responsibility." The provider submitted claims for service code G2023, for COVID-19 specimen collection. The Issuer did not provide CCIIO additional information regarding guidance given to providers about how to submit claims for items and services to indicate they are related to COVID-19 diagnostic testing.
Citations	Families First Coronavirus Response Act, Pub. L. 116-127, div. F § 6001(a)(1) and (2)
Corrective Action	**Corrective Actions:** Conduct a self-audit to identify all claims from January 1, 2021 to May 11, 2023 for procedure code G2023 that denied coverage or imposed cost sharing for COVID-19 diagnostic testing. Within 60 calendar days from the date of this final report, provide documentation containing the results from the self-audit, re-adjudicate all such claims and provide a list of the claims identified and re-adjudicated to CCIIO. Include the claim number, date of service, date of original denial or imposition of cost sharing, date of re-adjudication, amount paid to provider, provider reimbursement check number issued, amount refunded to member, and member refund check number issued on the date of re-adjudication.

V. Observation

Observation 1	
Summary	Using medical management techniques that are considered unreasonable, and not deferring to the determination of the attending provider. Exceptions process appears to be unduly burdensome on the individual or the provider. The Issuer stated that, for each of the identified claims, it identified covered formulary alternatives available to the member. If a member or prescriber requests a drug not listed on the Issuer's ACA preventive drug list, it is subject to the same utilization management criteria as other medications that are not listed on the formulary, including a prior authorization or coverage exception. When asked to demonstrate "an easily accessible, transparent, and sufficiently expedient exceptions process", the Issuer responded with a detailed explanation and a complete list of all pharmacy contraceptive claim exception requests received for the examination period, January 1, 2021 through September 30, 2021. Out of the 5,280 contraceptive claims rejected for denial reason code 70 - Product not covered, only 92 exception requests were submitted for 2021. Out of 92 exception requests submitted, only 77 were approved by the Issuer. For coverage of the contraceptive drug Slynd, the Issuer did not follow guidance regarding step-therapy within the same method for contraception. The Issuer required trial and failure of formulary options outside the drug classification of contraceptive requested. For the identified claims, the Issuer stated that the requesting provider did not include sufficient support to demonstrate why the requested item was medically necessary to waive the trial and failure step therapy requirement. This resulted in coverage denials for contraceptives, or cost-sharing applied to contraceptive claims for 1,086 claims.
FAQ Guidance	FAQs About Affordable Care Act Implementation (Part XXVI),(FAQ 26) issued May 11, 2015. FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and

Observation 1	
	Economic Security Act Implementation, Q9 (FAQ 51) issued January 10, 2022.

VI. Examination Results

A. Preventive Health Services Findings

Finding 1 – Violation of section 2713(a) of the PHS ACT, and 45 C.F.R. § 147.130(a)(1)

Section 2713(a) of the PHS Act states in pertinent part:

> (a) In General. —A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—
>
> > (1) evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force;
> >
> > (2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and
> >
> > (3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.
> >
> > (4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.
> >
> > (5) for the purposes of this Act, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.
>
> Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

45 C.F.R. § 147.130(a)(1), Coverage of preventive health services, states in pertinent part:

> (a) Services— (1) In general. Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131, 147.132, and 147.133, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration;

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131, 147.132, and 147.133; and

(v) Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved—

(A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or

(B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (regardless of whether the immunization is recommended for routine use). For purposes of this paragraph (a)(1)(v)(B), a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention.

Plans and issuers subject to section 2713(a) of the PHS Act must cover, without cost sharing, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately. Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 71142, 71174 (Nov. 2, 2020).

The Issuer failed to comply with the above requirements in the circumstances detailed in the findings below.

Preventive Health Services Findings

CCIIO requested the Issuer's claims data, focusing on those claims with ICD-10 diagnosis and/or CPT procedure codes that indicated the member received preventive services. CCIIO analyzed the Issuer's claims data and identified claims for which the Issuer denied coverage or applied cost sharing to the member. CCIIO then requested those claim files to review whether the Issuer improperly denied coverage or applied cost sharing. CCIIO received and reviewed these claim files for compliance with the regulations.

CCIIO identified claims indicating that the Issuer inappropriately denied coverage of preventive health services or applied cost sharing to preventive health services in two instances impacting two individuals. Claim files that contained violations for this finding are listed in the table below:

Area Reviewed	Population	Sample Size	Violations	% of Error
Pediatric Bright Futures & Immunization group denied claims	33,489	107	1	0.93%
HRSA Women's Preventive Services Guidelines group denied claims	8,553	216	1	0.46%

CCIIO identified potential violations and provided these to the Issuer in the form of criticisms. Criticisms #4, #5, and #6 identified those claims that indicated a service was preventive, and for which the Issuer denied payment or applied cost sharing. This impacted the following preventive health services:

- Criticism #4 – USPSTF: One claim for the screening of auditory potential with broadband stimuli (hearing testing);
- Criticism #5 –HRSA : Six claims for cervical cancer screening; two claims for depression screenings; ten claims for HPV testing; one claim for pregnancy testing; and
- Criticism #6 – HRSA: One claim related to HPV testing.

The Issuer agreed with Criticisms #4 and #6 for the screening of audit sensory potential with broadband stimuli and applying cost sharing to HPV testing. Because the Issuer agreed, these items are not addressed in the table below.

The Issuer disagreed with Criticism #5. The Issuer also disagreed that step therapy or prior authorization for contraceptive drugs may be considered unreasonable medical management. For these items, the Issuer stated the following:

Criticism 5	
Subject	Applying cost sharing to USPSTF A&B and Women's HRSA Preventive health services: Six claims for cervical cancer screening; two claims for depression screening; ten claims for HPV screening; and one claim for pregnancy testing. USPSTF A&B guidelines recommend screening for depression in the general adult population, including pregnant and postpartum women, and also recommend screening for chlamydia and gonorrhea in sexually active women age 24 years and younger and in older women who are at increased risk for infection. These claims were billed with the following diagnosis and procedure codes: 1. ICD-10 code R87.810 (Cervical high risk human papillomavirus (HPV) DNA test positive) and CPT code 87625 (Under Infectious Agent Antigen Detection: HPV Testing); 2. ICD-10 codes N92.6 (Irregular menstruation, unspecified) and Z34.91 (Encounter for supervision of normal pregnancy, unspecified, first trimester) and CPT code 87624 (Under Infectious Agent Antigen Detection: HPV Testing); 3. ICD-10 codes N926 (Irregular menstruation, unspecified) and Z3491 (Encounter for supervision of normal pregnancy,

Criticism 5	
	unspecified, first trimester) and CPT code 88175 (Under FNA Cytopathology Procedures); 4. ICD-10 code Z32.01 (Encounter for pregnancy test, result positive) and CPT code 84702 (Under Chemistry Procedures: Pregnancy Testing); 5. ICD-10 code Z13.89 (Encounter for screening for other disorder) and CPT code 96127 (Under Developmental and Behavioral Screening and Testing); 6. ICD-10 codes O09.529 (Supervision of elderly multigravida, unspecified trimester) and CPT code 87624 (Under Infectious Agent Antigen Detection: HPV Testing); 7. ICD-10 code F41.9 (anxiety disorder, unspecified) and CPT code 96127 (Under Developmental and Behavioral Screening and Testing); 8. ICD-10 code R87.619 (Unspecified abnormal cytological findings in specimens from cervix uteri) and 88175 (Under FNA Cytopathology Procedures); 9. ICD-10 code R87.619 (Unspecified abnormal cytological findings in specimens from cervix uteri) and CPT code 87624 (Under Infectious Agent Antigen Detection: HPV Testing); 10. ICD-10 code B97.7 (Papillomavirus as the cause of diseases classified elsewhere) and CPT code 87624 (Under Infectious Agent Antigen Detection: HPV Testing); 11. ICD-10 codes R31.9 (Hematuria, unspecified) R73.03 (Prediabetes), Z11.59 (Encounter for screening for other viral diseases) and Z11.2 (Encounter for screening for other bacterial diseases) and CPT code 87624 (Under Infectious Agent Antigen Detection: HPV Testing); 12. ICD-10 codes R31.9 (Hematuria, unspecified) R73.03 (Prediabetes), Z11.59 (Encounter for screening for other viral diseases) and Z11.2 (Encounter for screening for other bacterial diseases) and CPT code 87625 (Under Infectious Agent Antigen Detection: HPV Testing); 13. ICD-10 code R87.610 (Atypical squamous cells of undetermined significance on cytologic smear of cervix) and Z39.2 (Encounter for routine postpartum follow-up) and CPT code 88141 (Under Cytopathology Screening Procedures); 14. ICD-10 code R87.610 (Atypical squamous cells of undetermined significance on cytologic smear of cervix) and

Criticism 5	
	Z39.2 (Encounter for routine postpartum follow-up) and CPT code 88175 (Under FNA Cytopathology Procedures); 15. ICD-10 codes R87.610 (Atypical squamous cells of undetermined significance on cytologic smear of cervix) and Z39.2 (Encounter for routine postpartum follow-up) and CPT code 87624 (Under Infectious Agent Antigen Detection: HPV Testing); 16. ICD-10 code N92.1 (Excessive and frequent menstruation with irregular cycle) and CPT code 88175(Under FNA Cytopathology Procedures); 17. ICD-10 code N92.1 (Excessive and frequent menstruation with irregular cycle) and CPT code 87624 (Under Infectious Agent Antigen Detection: HPV Testing); 18. ICD-10 code R87.622 (Low grade squamous intraepithelial lesion on cytologic smear of vagina (LGSIL) and CPT code 88175 (Under FNA Cytopathology Procedures); and 19. ICD-10 R87.622 (Low grade squamous intraepithelial lesion on cytologic smear of vagina (LGSIL) and CPT code 87624 (Under Infectious Agent Antigen Detection: HPV Testing).
Citation	Section 2713(a) of the PHS Act and 45 C.F.R. § 147.130(a)(1)
Issuer Response	The Company respectfully disagrees with the criticism. UnitedHealthcare covers, without cost-sharing, preventive care services consistent with the requirements of the Patient Protection and Affordable Care Act (ACA), ACA implementing regulations, and applicable state law. Federal law expressly permits the use of reasonable medical management techniques in determining the frequency, method, treatment, or setting for coverage of a recommended preventive health service when not specified in a recommendation or guideline. Federal law also expressly permits the imposition of cost-sharing requirements for treatments which are not described as part of a preventive recommendation or guideline. 29 CFR §§ 2590.715(a)(4) & (5), 45 CFR §§ 147.130(a)(4) & (5), and 26 CFR §§ 54.9815-2713(a)(4) & (5). For example, the US Preventive Services Task Force recommendations do not apply to services for patients with obvious related signs or symptoms. See, e.g., USPSTF Final Recommendation Statement, Cervical Cancer: Screening (Preface).

Criticism 5	
	UnitedHealthcare's Preventive Care Services Coverage Determination Guideline (Preventive CDG) outlines the procedure and diagnosis codes that a provider should bill for a particular test or screening to be considered for adjudication under the plan's preventive care benefit and covered without cost sharing. If a test or screening claim does not include the procedure and diagnosis codes described in the Preventive CDG, the test or screening will be considered under the plan's standard medical benefit and subject to applicable cost sharing provisions.
CCIIO Response	CCIIO finds the Issuer's response sufficient to remove all findings related to Criticism #5. 45 C.F.R. § 147.130(a)(1) defines the requirement for certain recommended preventive health services to be covered by health plans without imposing cost sharing.

Issuer's Response:

Within 90 calendar days from the date of receipt of the final report, UHIC will provide documentation containing the results from the self-audit, re-adjudicate all such claims and provide a list of the claims identified and re-adjudicated to CCIIO. This list will include the claim number, date of service, date of original denial or imposition of cost sharing, date of re-adjudication, amount paid to provider, provider reimbursement check number issued, amount refunded to member, and member refund check number issued on the date of re-adjudication. Updates to the existing claim policy is not necessary due to the manual processing errors of the cited claims which did not conform to the applicable policy.

CCIIO concurs with the Issuer's position.

Corrective Actions:

Conduct a self-audit to identify all claims from January 1, 2021 through the date this final report is issued for service codes 92650 and 87625 that denied coverage or imposed cost sharing and for which the Issuer did not provide guidance to providers about how to submit claims to indicate the furnished items and services are recommended preventive items or services.

Within 90 calendar days from the date of this final report, provide documentation containing the results from the self-audit, re-adjudicate all such claims, and provide a list

of the claims identified and the results of any re-adjudications to CCIIO. Include claim number, date of service, date of original denial or imposition of cost sharing, date of re-adjudication, amount paid to provider, provider reimbursement check number issued, amount refunded to member, and member refund check number issued on the date of re-adjudication.

Review and update claim policies to ensure compliance with all Federal preventive health services statutes and rules. Provide the updated claim policies to CMS within 90 calendar days from the date of this final report.

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B. COVID-19 Diagnostic Testing Finding

Finding 2 – Families First Coronavirus Response Act, Pub. L. 116-127, div. F § 6001(a)(1) and (2), as amended, states in pertinent part:

> (a) In General.--A group health plan and a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall provide coverage, and shall not impose any cost-sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements, for the following items and services furnished during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b-5(g)) beginning on or after the date of the enactment of this Act:
>
> > (1) An in vitro diagnostic test defined in section 809.3 of title 21, Code of Federal Regulations (or successor regulations) for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19, and the administration of such a test, that—
> >
> > > (A) is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and
> > >
> > > Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3);
> > >
> > > (B) the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), unless and until the emergency use authorization request under such section 564 has been denied or the
> > >
> > > developer of such test does not submit a request under such section within a reasonable timeframe;
> > >
> > > (C) is developed in and authorized by a State that has notified the Secretary of Health and Human Services of its intention to review tests intended to diagnose COVID–19; or
> > >
> > > (D) other test that the Secretary determines appropriate in guidance.''
> >
> > (2) Items and services furnished to an individual during health care provider office visits (which term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product described in paragraph (1), but only to the extent

such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product.

The Issuer failed to comply with the above requirements in the circumstances detailed in the finding below.

COVID-19 Diagnostic Testing Finding

The Issuer failed to provide coverage of items and services related to COVID-19 diagnostic testing without cost sharing for one procedure billed in the group market. COVID-19 diagnostic testing services were reviewed as part of the claim population provided by the Issuer related to Immunizations and Pediatric Bright Futures claims. Claim file that contained violation for this finding are listed below.

CCIIO identified a claim indicating that the Issuer inappropriately denied coverage of qualifying COVID-19 diagnostic testing or applied cost sharing to items and services related to COVID-19 diagnostic testing in one instance. The claim file that contained violation for this finding are listed in the table below:

Area Reviewed	Population	Sample Size	Violations	% of Error
USPSTF A & B group paid claims	731,792	183	1	0.55%

CCIIO organized its review, identifying potential violations, and provided these to the Issuer in the form of criticisms. Criticisms #1, #2, and #3, identified those claims that indicated a service was related to COVID-19 diagnostic testing, and for which the Issuer denied or applied cost sharing. This impacted the following services:

- Criticism #1 – Families First Coronavirus Response Act: Two claims for which the Issuer requested member medical records in order to process COVID-19 testing claims;
- Criticism #2 – Families First Coronavirus Response Act: Six claims for which the Issuer requested member medical records in order to process COVID-19 testing claims; and
- Criticism #3 – Families First Coronavirus Response Act: One claim for which cost sharing was applied to the member's deductible for a COVID-19 test.

The Issuer agreed with the COVID-19 testing items in Criticism #3. Because the Issuer agreed, this item is not addressed in the table below.

The Issuer disagreed with the items in Criticism #1 and #2. For these items, the Issuer stated the following:

Criticism 1	
Subject	Applying medical management requirements to Families First Coronavirus Response Act services: Two claims for which the Issuer requested member medical records to process COVID-19 testing claims. The Families First Coronavirus Response Act requires coverage of and prohibits cost-sharing or the application of prior authorization or other medical management requirements for specific services furnished during any portion of the emergency period, including in vitro diagnostic products for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19.
Citation	Families First Coronavirus Response Act, Pub. L. 116-127, div. F § 6001(a)(1) and (2)
Issuer Response	The Company respectfully disagreed with this Criticism. The claims were pended, and medical records were requested due to an analytic that identified a potential issue with provider billing (potential Fraud, Waste, Abuse, Error). The provider did not respond within the required time frame for either claim, thus the claims were denied for non-receipt of information. This was a participating provider, hence no financial liability for the patient.
CCIIO Response	CCIIO finds the Issuer's response sufficient to remove the finding for the two items in Criticism #1. The request for medical records for these claims was reasonable, as they were flagged for potential fraud, waste, and abuse, and the provider did not timely respond to the request.

Criticism 2	
Subject	Applying medical management requirements to Families First Coronavirus Response Act services: Six claims for which the Issuer requested member medical records to process COVID-19 testing claims. The Families First Coronavirus Response Act requires coverage of and prohibits cost-sharing or the application of prior authorization or other medical management requirements for specific services furnished during any portion of the emergency period, including in vitro diagnostic products for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19.

Criticism 2	
Citation	Families First Coronavirus Response Act, Pub. L. 116-127, div. F § 6001(a)(1) and (2)
Issuer Response	The Company respectfully disagreed with this Criticism. The six claims were pended, and medical records were requested due to an analytic that identified a potential issue with provider billing (potential Fraud, Waste, Abuse, Error). The provider did not respond within the required timeframe for any of these claims, thus the claims were denied for non-receipt of the medical records requested. The EOBs show that the claims were denied because the medical records were not received. If the insured is able to obtain medical records and submit them to us, or the provider subsequently submits the medical records, the claims can be reconsidered for payment.
CCIIO Response	CCIIO finds the Issuer's response sufficient to remove the finding for the six items in Criticism #2. The request for medical records for these claims was reasonable, as they were flagged for potential fraud, waste, and abuse, and the provider did not timely respond to the request.

Issuer Response:

Within 60 calendar days from the date of receipt of the final report, UHIC will provide documentation containing the results from the self-audit, re-adjudicate all such claims and provide a list of the claims identified and re-adjudicated to CCIIO. This list will include the claim number, date of service, date of original denial or imposition of cost sharing, date of re-adjudication, amount paid to provider, provider reimbursement check number issued, amount refunded to member, and member refund check number issued on the date of re-adjudication. Updates to the existing claim policy is not necessary due to the manual processing error of the cited claim which did not conform to the applicable policy.

CCIIO concurs with the Issuer's position.

Corrective Actions

Within 60 calendar days from the date of this final report, perform a self-audit to identify all claims from January 1, 2021 to May 11, 2023 for service code G2023 that denied coverage or imposed cost sharing and for which the Issuer did not provide guidance to providers about how to submit claims for items and services to indicate they are related to COVID-19 diagnostic testing.

Re-adjudicate all such claims and provide a list of the claims identified and the results of any re-adjudications to CCIIO. The results shall contain the claim number, date of service, date of original denial or imposition of cost sharing, date of re-adjudication, amount paid to provider, provider reimbursement check number issued, amount refunded to member, and member refund check number issued on the date of re-adjudication.

VII. Observations

A. Preventive Health Services Observation

Observation 1 – The following guidance has been issued by CMS concerning contraceptive drug and device cost sharing:

FAQS About Affordable Care Act Implementation (Part XXVI), (FAQ 26) issued May 11, 2015, states in pertinent part:

> *Coverage of Food and Drug Administration (FDA)-approved Contraceptives*
>
> These FAQs provide further guidance on the scope of coverage required for contraception and the extent to which plans and issuers may utilize reasonable medical management. Specifically:
>
> 1. Plans and issuers must cover without cost sharing at least one form of contraception in each of the methods (currently 18) that the FDA has identified for women in its current Birth Control Guide.[12] This coverage must also include the clinical services, including patient education and counseling, needed for provision of the contraceptive method.
>
> 2. Within each method, plans and issuers may utilize reasonable medical management techniques. A plan or issuer generally may impose cost sharing (including full cost sharing) on some items and services to encourage an individual to use other specific items and services within the chosen contraceptive method. For example, a plan may discourage use of brand name pharmacy items over generic pharmacy items through the imposition of cost sharing. Similarly, a plan may use cost sharing to encourage use of one of several FDA-approved intrauterine devices (IUDs) with progestin.
>
> 3. If utilizing reasonable medical management techniques within a specified method of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative).
>
>   a. If an individual's attending provider[13] recommends a particular service or FDA- approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The plan or issuer must defer to the determination of the attending provider. Medical necessity may include considerations such as severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to

the appropriate use of the item or service, as determined by the attending provider

[12] The contraceptive methods for women currently identified by the FDA include: (1) sterilization surgery for women; (2) surgical sterilization implant for women; (3) implantable rod; (4) IUD copper; (5) IUD with progestin; (6) shot/injection; (7) oral contraceptives (combined pill); (8) oral contraceptives (progestin only); (9) oral contraceptives extended/continuous use; (10) patch; (11) vaginal contraceptive ring; (12) diaphragm; (13) sponge; (14) cervical cap; (15) female condom; (16) spermicide; (17) emergency contraception (Plan B/Plan B One Step/Next Choice); and (18) emergency contraception (Ella). The FDA Birth Control Guide additionally lists sterilization surgery for men and male condoms, but the HRSA Guidelines exclude services relating to a man's reproductive capacity. See Preamble to Proposed Rules regarding coverage of certain preventive services at 78 FR 8458 (February 6, 2013). See also FDA Birth Control Guide at http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM356451.pdf. See also FDA publication, "Birth Control: Medicines to Help You," available at http://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm#Hormonal_Methods.

[13] An attending provider means an individual who is licensed under applicable state law, who is acting within the scope of the provider's license, and who is directly responsible for providing care to the patient relating to the recommended preventive services. Therefore, a plan, issuer, hospital, or managed care organization is not an attending provider.

FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Q9 (FAQ 51) issued January 10, 2022 states in pertinent part:

> Q9: What is expected of non-exempt[39] plans and issuers regarding compliance with the requirement to cover contraceptive services under PHS Act section 2713?
>
> The Departments have received a number of complaints and reports that participants, beneficiaries, and enrollees are being denied contraceptive coverage in violation of the requirements under PHS Act section 2713. Examples include plans and issuers, as well as their pharmacy benefits managers:
>
> • Denying coverage for all or particular brand name contraceptives, even after the individual's attending provider determines and communicates to the plan or issuer that a particular service or FDA-approved, cleared, or granted contraceptive product is medically necessary with respect to that individual;
>
> • Requiring individuals to fail first using numerous other services or FDA-approved, cleared, or granted contraceptive products within the same method of contraception before the plan or issuer will approve coverage for the service or FDA-approved, cleared, or granted contraceptive product that is medically appropriate for the individual, as determined by the individual's attending health care provider;

• Requiring individuals to fail first using other services or FDA-approved, cleared, or granted contraceptive products in other contraceptive methods before the plan or issuer will approve coverage for a service or FDA-approved, cleared, or granted contraceptive product in the contraceptive method that is medically appropriate for the individual, as determined by the individual's attending health care provider; and

• Failing to provide an easily accessible, transparent, and sufficiently expedient exception process that is not unduly burdensome (for example, requiring individuals to appeal an adverse benefit determination using the plan's or issuer's internal claims and appeals process as the means to obtain an exception).

[39] On November 15, 2018, the Departments published final regulations concerning religious exemptions at 83 FR 57536 and moral exemptions at 83 FR 57592, as well as accommodations regarding this coverage. On August 16, 2021, the Departments issued FAQs about Affordable Care Act Implementation Part 48, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-48.pdf and https://www.cms.gov/files/document/faqs-part-48.pdf, in which the Departments indicated their intent to initiate rulemaking within six months of that date to amend these final regulations.

Preventive Health Services Observations

Using medical management techniques that are considered unreasonable, and not deferring to the determination of the attending provider.

Area Reviewed	Population	Sample Size	Observations
Policy and Procedure documents, Claim Processing documents, Provider Manuals, and other miscellaneous documents provided by the Issuer	N/A	40	2
Pharmacy group paid claims	286,478	107	4
Pharmacy Women's Contraceptive - reject reason code 75 (prior authorization)	51	51	51
Pharmacy Women's Contraceptive - reject reason code 806 (step therapy)	1,086	1,086	1,086

The Issuer's pharmacy exception policy defines clinical review as the sole review activity for exception requests. There is no other review process identified by the Issuer's documentation.

In response to Request for Information (RFI) 12R2, the Issuer provided the "UnitedHealthcare Pharmacy Policy & Procedure" document, which states in pertinent part on page one, item "b" under "II Policy," "For patients who do not tolerate or have a contraindication to zero cost-sharing agents, a clinical review will be performed to determine coverage of a cost-sharing agent at zero copayment, coinsurance or deductible."

45 C.F.R. § 147.130(a)(4) generally states that nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for a preventive item or service to the extent not specified in the relevant recommendation or guideline. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) have issued several sets of FAQs regarding contraceptive coverage to clarify what the Departments consider to be necessary elements for medical management techniques to be considered reasonable under 45 C.F.R. 147.130(a)(4). On February 20, 2013, the Departments issued *Affordable Care Act Implementation FAQs – Set 12* stating in response to Q14:

> … plans and issuers may use reasonable medical management techniques to control costs and promote efficient delivery of care. For example, plans may cover a generic drug without cost-sharing and impose cost-sharing for equivalent branded drugs. However, in these instances, a plan or issuer must accommodate any individual for whom the generic drug (or a brand name drug) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost-sharing for the branded or non-preferred brand version.

On May 11, 2015, the Departments issued FAQ 26 to further clarify what constitutes reasonable medical management for individuals for whom a particular item or service would be medically inappropriate. FAQ 26 states in pertinent part:

> If utilizing reasonable medical management techniques within a specified method of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative). If an individual's attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The plan or issuer must defer to the determination of the attending provider. Medical necessity may include considerations such as severity of side effects, differences in permanence and reversibility of

> contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider.

In this case, the Issuer's policy does not satisfy the FAQ guidelines for reasonable medical management.

This policy does not meet the stated requirement in FAQ 26 that "The plan or issuer must defer to the determination of the attending provider."

The Issuer disagreed with the observation stating:

> The UnitedHealthcare $0 Cost-share Exception Request process does not evaluate the basis for the provider's determination of medical necessity. Exception requests are approved when there is a provider statement or clinical records indicating the product is for birth control or contraception. If purpose for use is not clearly stated, UnitedHealthcare clinical reviewers examine the records to discern the purpose for use. "Clinical review" at paragraph 11.B in the UnitedHealthcare Pharmacy Policy & Procedure document is a reference to this process of using a clinical review team to look for information within the submitted medical records on which to approve the Exception Request.
>
> UnitedHealthcare is committed to ensuring that our members have timely and affordable access to FDA-approved contraceptives when they need them. We continue to look for opportunities to improve educational materials about our Exception Request process to make it even easier and more transparent for members and providers.

CCIIO also observed the following scenarios where pharmacy contraceptive claims were inappropriately rejected.

- The prescription was filled at the point of sale, but the member was billed cost sharing.

- The prescription was rejected at the point of sale and not filled for reasons such as drug not covered and prior authorization required.

Pharmacy claims are processed differently than medical claims due to the real time decision process required at the point of sale (POS). Pharmacy claims are submitted electronically prior to the service (drug) being provided to the member. Pharmacy claims are categorized as P (Paid) or R (Rejected).

- Rejections occur at the POS if the member if not eligible, if the pharmacy is not contracted with the Issuer, or if the drug is not a covered benefit of the member's plan.

- Pharmacy claims that require prior authorization are rejected initially, but if the Issuer approves a prior authorization request, the pharmacy can reverse the rejection, and the claim will be paid (and the prescription filled). Prior authorization requests that are denied by the Issuer result in an Adverse Determination Letter being sent to the member, and the original rejected claim remains rejected, unpaid, and unfilled.

The Issuer's Prescription Drug List (PDL) contains a footnote that states:

> When informed by a member's health care provider, UnitedHealthcare will accommodate a coverage exception request for any member when one of the $0 cost medications listed on the Preventive Care Medications list may be medically inappropriate as determined by the health care provider for that member and UnitedHealthcare will waive the otherwise applicable cost-sharing for a medication not represented on the Preventive Care Medications list.

However, as part of this investigation, CCIIO requested that the Issuer provide a detailed explanation with supporting documentation regarding paid claims for contraceptives where the members incurred cost sharing.

The Issuer's response stated in pertinent part:

> …members met prior authorization and step therapy criteria and received an approval for coverage of Slynd…These approvals were for coverage at the standard cost-share for the drug. An exception request for $0 cost-share was not received for these members.

Regarding unpaid Slynd claims, CCIIO requested that the Issuer provide a detailed explanation with supporting documentation on the following:

> Of 1,325 Slynd claim data records received, 1,086 claims rejected for denial reason code 608 - Step Therapy. For each item listed in Exhibit 6, provide a detailed response, with supporting documentation, that explains how Step Therapy supports the requirement for "an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider".

The Issuer's response stated in pertinent part:

> Slynd is an oral contraceptive (progestin only) that should be used when estrogen-containing contraceptives are contraindicated and the prescriber has confirmed the benefits of drospirenone-containing, progestin-only contraceptives outweigh the potential risk of venous thromboembolism (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211367s000lbl.pdf) . Due to safety concerns with the use of Slynd and lower cost options, other

progestin-only contraceptives, such as norethindrone, are covered at zero-cost share. See the attached zip file titled “TX CMS Preventive Lists”.

FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Q9 (FAQ 51) issued January 10, 2022 states in pertinent part:

> … the HRSA Guidelines, as interpreted in the Departments’ implementing regulations and guidance, including the requirement that, if an individual and their attending provider determine that a particular service or FDA-approved, cleared, or granted contraceptive product is medically appropriate for the individual (whether or not the item or service is identified in the current FDA Birth Control Guide), the plan or issuer must cover that service or product without cost sharing.

To demonstrate how the Issuer complies with the requirement to provide “an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or provider”, the Issuer was requested to provide a comprehensive explanation with supporting documentation on the UHC of TX Exception Process for Contraceptives. In addition, the Issuer was asked to provide a complete list of all pharmacy contraceptive claim exception requests received during the examination period, January 1, 2021 through September 30, 2021.

The Issuer responded in pertinent part:

> UnitedHealthcare accepts Exception requests submitted by members or their providers. Exception requests can be submitted and approved before a claim is denied or processed with cost-sharing. Exception requests can also be approved retroactively with reimbursement to the member.
>
> Exception requests are approved when there is a provider statement or clinical records showing the provider’s determination that the particular contraceptive product is needed by the member for the purpose of contraception (versus, for example, to manage heavy periods/bleeding). UnitedHealthcare does not evaluate the basis for the provider’s determination.

This listing was provided in the attached spreadsheet titled “2021 CME TMCE UHIC_RFI 12R2 – Exception Request Data”. An analysis was performed on the complete listing provided by the Issuer for the contraceptive claim exception request listing received during the examination period. This listing was compared to the contraceptive claims and denials provided in the Rx data. Out of the 5,280 contraceptive claims rejected for denial reason code 70 - Product not covered only 92 exception requests were submitted for 2021. Out of 92 exception requests submitted, only 77 were approved by the Issuer.

The Issuer requires medical records to prove medical necessity, and The Issuer's policy and procedures indicate a clinical review is performed. The Issuer's policies and procedures do not appear to follow the sub-regulatory guidance which states that members should have easily accessible, transparent, and expedient exceptions process that is not burdensome to the individual or provider.

In addition, the Issuer did not provide supporting documentation that prior step therapy processes for contraceptives not included as without cost sharing on the formulary were managed in compliance with sub-regulatory guidance FAQ 26, Q1 and Q2 and FAQ 51, Q9.

A search of www.uhcprovider.com, the Issuer's website for providers and health care professionals, found the UnitedHealthcare Pharmacy Clinical Pharmacy Program's step therapy program for the contraceptive drug Slynd (drospirenone) (https://www.uhcprovider.com/content/dam/provider/docs/public/resources/pharmacy/step-therapy/Step-Therapy-Slynd.pdf). The document provides the following as background information and instruction for the progesterone-only contraceptive regarding UHC's step therapy program requirements and coverage criteria:

1. Background:

   Oral contraceptives are available as either combination estrogen/progesterone-containing contraceptives or as progesterone-only contraceptives. Progesterone-only contraceptives should be used when estrogen-containing contraceptives are contraindicated. Slynd (drospirenone) is a progesterone-only contraceptive indicated for use by females of reproductive potential to prevent pregnancy.

   Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try a lower cost contraceptive before providing coverage for Slynd.

2. Coverage Criteria:

   A. Slynd will be approved based on all the following criteria:

      1. History of failure, contraindication, or intolerance to both of the following medications:
      a. an estrogen/progesterone containing contraceptive [e.g., norgestimate/ethinyl estradiol (generic Ortho Cyclen), Yaz]

      -AND-

      b. a progesterone-only contraceptive [(i.e. norethindrone (generic Ortho Micronor)]

Authorization will be issued for 12 months.

a. State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

A review of the Issuer's Rx data list noted 51 claims for the contraceptive Slynd that were denied because prior authorization was required, and 4 Slynd claims that were rejected due to the product not being covered.

The medical management policies applied to the claim adjudication of Slynd claims are contrary to FAQ 26, as well as "FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation" (FAQ 51), issued January 10, 2022, Q9: which states in pertinent part:

> Q9: What is expected of non-exempt plans and issuers regarding compliance with the requirement to cover contraceptive services under PHS Act section 2713? The Departments have received a number of complaints and reports that participants, beneficiaries, and enrollees are being denied contraceptive coverage in violation of the requirements under PHS Act section 2713. Examples include plans and issuers, as well as their pharmacy benefits managers:
>
> • Denying coverage for all or particular brand name contraceptives, even after the individual's attending provider determines and communicates to the plan or issuer that a particular service or FDA-approved, cleared, or granted contraceptive product is medically necessary with respect to that individual;
>
> • Requiring individuals to fail first using numerous other services or FDA approved, cleared, or granted contraceptive products within the same method of contraception before the plan or issuer will approve coverage for the service or FDA-approved, cleared, or granted contraceptive product that is medically appropriate for the individual, as determined by the individual's attending health care provider;
>
> • Requiring individuals to fail first using other services or FDA-approved, cleared, or granted contraceptive products in other contraceptive methods before the plan or issuer will approve coverage for a service or FDA-approved, cleared, or granted contraceptive product in the contraceptive method that is medically appropriate for the individual, as determined by the individual's attending health care provider; and
>
> • Failing to provide an easily accessible, transparent, and sufficiently expedient exception process that is not unduly burdensome (for example,

requiring individuals to appeal an adverse benefit determination using the plan's or issuer's internal claims and appeals process as the means to obtain an exception).

The Issuer disagreed with the observation and stated:

> The Company respectfully disagrees with the criticism.
>
> The UnitedHealthcare $0 Cost-share Exception Request process does not evaluate the basis for the provider's determination of medical necessity. Exception requests are approved when there is a provider statement or clinical records indicating the product is for birth control or contraception. If purpose for use is not clearly stated, UnitedHealthcare clinical reviewers examine the records to discern the purpose for use. "Clinical review" at paragraph 11.B in The UnitedHealthcare Pharmacy Policy & Procedure document is a reference to this process of using a clinical review team to look for information within the submitted medical records on which to approve the Exception Request.
>
> UnitedHealthcare is committed to ensuring that our members have timely and affordable access to FDA-approved contraceptives when they need them. We continue to look for opportunities to improve educational materials about our Exception Request process to make it even easier and more transparent for members and providers.
>
> 42 U.S.C.§ 30099-13, 45 C.F.R. § 147.130, and related federal guidance allow health plans and issuers to use reasonable medical management. Consistent with federal requirements, UnitedHealthcare has an easily accessible, transparent, and expedient process for members or their providers to request coverage without cost sharing for a particular contraceptive product that is otherwise subject to reasonable medical management. FAQ 51 identifies examples of failing to provide coverage without cost sharing as required through an exception process. FAQ 51 does not prohibit health plans and issuers from using step therapy as a type of reasonable medical management technique permitted under federal law and regulation.

CCIIO Response:

CCIIO continues to have concerns about the transparency and expedience of the exceptions process.

Notwithstanding the Issuer's response, the written policy is not consistent with guidance regarding reasonable practices because the Issuer's exceptions process does not defer to the determination of the attending provider by requiring processes such as clinical review. The Issuer's statement that "If purpose for use is not clearly stated,

UnitedHealthcare clinical reviewers examine the records to discern the purpose for use" is not supported by the UnitedHealthcare Pharmacy Policy & Procedure (P&P) document provided by the Issuer. The P&P document states in pertinent part:

> II. Policy
>
> * * * *
>
> B. In an effort to make contraception available to members while controlling costs, UHCP provides a comprehensive selection of contraceptives to members via the pharmacy benefit at zero cost-share without prior authorization. For patients who do not tolerate or have a contraindication to zero cost-sharing agents, a clinical review will be performed to determine coverage of a cost-sharing agent at zero copayment, coinsurance, or deductible.

The P&P indicates that clinical review is an integral part of the exception process and is not limited to those instances where the purpose of use is not clearly identified by the provider submitting the exception request. The language in the P&P indicates a clinical review will be performed for all patients who do not tolerate or have a contraindication. It does not describe any exception to this requirement for clinical review or explain that the Exception Request process defers to the provider's medical necessity determination. The written policy of performing a clinical review of exception requests for patients who do not tolerate or have a contraindication to zero cost-sharing agents for whom a provider has made a determination of medical necessity demonstrates that the Issuer does not defer to the determination of the attending provider, consistent with FAQ 26. Based on the Issuer's response, the Issuer is deferring to the determination of the attending provider in practice, but the Issuer should update the written policy and procedures to more clearly reflect what occurs in operation.

The Issuer's process does not appear to constitute an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider. The Issuer was asked to provide all documentation, including provider and member correspondence for claims included in the claims sample. This example is in reference to a requested pharmacy claim for a non-formulary contraceptive that was approved through the Issuer's prior authorization process, however, cost sharing was billed to the member. When asked to provide a detailed explanation of why cost sharing was applied to the member's prescription, including all provider and member correspondence, the provider failed to provide the prior authorization request submitted by the provider for the claim. The Issuer provided a written response that the member was billed cost sharing because the provider did not request an exception to cost sharing.

The Issuer did not explain how the receipt of a prior authorization request related to contraceptive services did not satisfy their plan documentation (formulary) statement that "When informed by a member's health care provider, UnitedHealthcare will

accommodate a coverage exception request for any member when one of the $0 cost medications listed on the Preventive Care Medications list may be medically inappropriate as determined by the health care provider for that member and UnitedHealthcare will waive the otherwise applicable cost sharing for a medication not represented on the Preventive Care Medications list."

The Issuer did not provide evidence of a distinction between the prior authorization and exception processes. The two processes appear ambiguous and conflated.

The Issuer's response demonstrates that the Issuer requires a separate exception request in addition to a prior authorization request to waive cost sharing for a contraceptive drug that requires prior authorization.

During the Examination, a request was submitted to the Issuer to provide "All files and documents including provider manuals, member materials, claim processing guides, website content (captured in pdf document form) containing instructions and contact information for submitting an exception request." In response, the Issuer provided a one-page PDF document without any explanation of how the member or provider would be aware that the document exists. The document, titled *"Patient Protection and Affordable Care Act $0 Cost-Share Preventive Medications Exemption Requests (UnitedHealthcare Commercial Members)"* states exemption (not exception) requests may be submitted by providers via fax or via mail to a P.O. Box. There is no form provided, and the document states "…the request should include the following information:

- What the medication will be used for (e.g. a contraceptive drug will be used for contraceptive purposes, or gonococcal ophthalmia neonatorum prevention (GON).

- Medical records (e.g. chart notes, lab values) showing that the medication is medical necessary for the patient, or for some preventive medications, whether other alternatives have been previously attempted."

Another request was submitted to the Issuer to "Provide all claims handling manuals, internal bulletins and guidelines issued by the Issuer with respect to the processing and payment of claims utilized at any point during the Examination Period." The Issuer provided a *"Preventive Care Services Coverage Determination Guide"* that indicates there are some preventive services that require prior authorization, but the Issuer did not provide the prior authorization process as part of their response, and the guide does not contain any references to an exception request process for contraceptive drugs.

The Issuer also provided a customer service standard operating procedure (SOP) document titled *ii. Customer Service SOP – HCR (OTC and RX Contraceptives)* in PDF format. This document instructs customer service representatives to:

- Advise member their provider can submit an exemption request for the medication by fax: 801-994-1345.

- Refer to Patient Protections and Affordable Care Act $0 Cost-Share Preventive Medications Exemption Requests (UnitedHealthcare Commercial Members) for more information.

Note: Only provide the urgent fax number if the member needs a resolution faster than standard appeal TATs.

This SOP refers to the policy document in the preceding paragraphs that include the submission of “Medical records (e.g. chart notes, lab values) showing that the medication is medically necessary for the patient…” a procedure more commonly included as a requirement for prior authorization requests.

A search of uhc.com, the Issuer’s website for members and providers, did not find an exception (or exemption) request on public facing pages (those web pages accessible without requiring the user to register for access). The public member pages of the site did include an FAQ that instructed the member to contact OptumRx to request that OptumRx contact the member’s provider to verify a prior authorization, but there were no FAQs or other instructions for requesting an exception for cost sharing for contraceptive drugs.

The Issuer did not provide evidence of a distinction between the prior authorization and exception processes. A separate exception request is required to “inform” the Issuer that the member (or their provider) is also requesting a waiver of cost sharing for a member when a prior authorization request has been submitted by the member’s provider for a medically appropriate contraceptive.

This example demonstrates that the Issuer requires a separate exception request in addition to a prior authorization request to waive cost sharing for a contraceptive drug that requires prior authorization. By requiring two separate processes for contraceptive coverage – one (prior authorization) for coverage of contraception, and one for waiver of cost sharing – the Issuer does not provide an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative), and therefore, there are continued concerns that the Issuer’s medical management techniques are not reasonable.

FAQ 26 states in pertinent part, “If utilizing reasonable medical management techniques within a specified method of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative). If an individual’s attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with

respect to that individual, the plan or issuer must cover that service or item without cost sharing. The plan or issuer must defer to the determination of the attending provider."

The Issuer did not provide supporting documentation to demonstrate compliance. Therefore, CCIIO observes that the Issuer's medical management techniques are not reasonable.

The contraceptive drug Slynd is listed on the Issuer's plan formulary as a Tier 4 (may be covered on Tier 4 in select benefits) drug that requires both prior authorization and step therapy for approval. The Issuer did not provide any medical management policy documentation that provides the requirements to satisfy the step therapy requirement.

Medical management, including prior authorization and step therapy, are allowed under 45 C.F.R. §147.130(a)(4), FAQ 26, Q1 and Q2 and FAQ 51, Q9. However, FAQ 51, Q9 specifically elaborates regarding complaints received from plan participants that Issuers are "requiring individuals to fail first using numerous other services or FDA-approved, cleared, or granted contraceptive measures within the same method of contraception before the plan or issuer will approve coverage for the service…"

Slynd is a progesterone-only oral contraceptive. Under the HRSA guidelines that point to the FDA classifications for contraception, there are three classifications of oral contraceptives, combined oral pill (estrogen and progesterone), progesterone-only pill, and the extended (long lasting) pill.

Using a step therapy or in an exceptions process, it would not be considered reasonable medical management for a plan or issuer to require a consumer to try or show contraindications for items or services outside of the contraception classification being requested (in this case Slynd is a progesterone-only pill). Therefore, the issuer's step therapy requirement to show a history of contraindications or reactions to a combined oral pill is not reasonable medical management and should be shown as a violation of federal requirements.

FAQ 26 states in pertinent part, "If utilizing reasonable medical management techniques within a specified method of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative). If an individual's attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The plan or issuer must defer to the determination of the attending provider."

The Issuer did not provide supporting documentation to demonstrate compliance for 1,086 claims. Therefore, CCIIO observes that the Issuer's medical management techniques are not reasonable.

VIII. Closing

A total of 2,753 claim files and documents were reviewed as part of this Examination. Of the claim files and documents reviewed, CCIIO found one violation affecting two individuals related to coverage of preventive health services and one violation affecting one individual related to coverage of COVID-19 diagnostic testing.

IX. Examination Report Submission

The courtesy and cooperation extended by the officers and employees of the Issuer during the course of the Examination are hereby acknowledged.

Jeffrey C. Wu -S Digitally signed by Jeffrey C. Wu -S
Date: 2024.11.04 18:02:42 -05'00'

Jeff Wu,
Deputy Director for Policy

Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services
US Department of Health & Human Services

In addition, the following individuals participated in this Examination and in the preparation of this report:

Center for Consumer Information and Insurance Oversight

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Examination Resources, LLC