

ADDENDUM 9

**Non-Risk Payment Arrangement ~ SMA,
Hepatitis C y Synthroid**

ADMINISTRACION DE
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Contrato Número



Non-Risk
Payment
Arrangement for
Hepatitis C,
Synthroid and
SMA Medications
Standard Operating
Procedure

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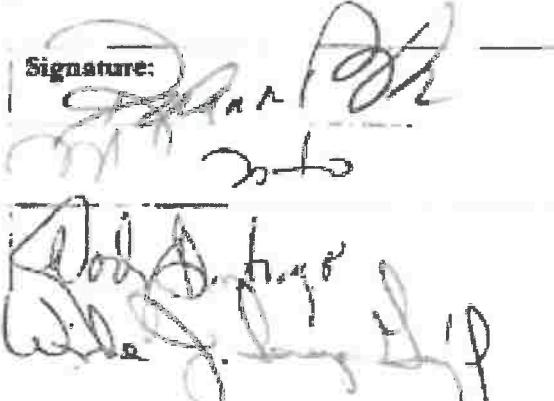
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General Information

Required Information	Description	Signature
Owner:	ASES	
Date:	7/01/2023	
Approved by:	Roxanna K. Roxario Acting Executive Director Milagros Soto Mejia Clinical Operations Director Carmen L. Rodriguez Santiago Assistant Finance Director Winda Lorenzo Acting Chief Information Officer	

Document Revision History

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v 1.0	7/01/2023	First version published for review.

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Acronyms and Terms

The following table provides definitions for acronyms and terms used in this document.

Acronym	Definition
ASES/PRHIA	Puerto Rico Health Insurance Administration
Centers for Medicare & Medicaid Services (CMS)	The Centers for Medicare & Medicaid Services is the agency within the US Department of Health and Human Services (HHS). It manages the nation's major health care programs. CMS oversees programs including Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the state and federal health insurance marketplaces. CMS collects and analyzes data, produces investigative reports, and works to eliminate cases of fraud and abuse within the health system.
Enterprise System (ES)	It is a system for collecting and managing data from various sources to provide meaningful business information. A data warehouse is typically used to connect and analyze business data from heterogeneous sources.
Food and Drug Administration (FDA)	Entity responsible for protecting public health by regulating human and veterinary drugs, vaccines and other biological products, medical devices, the food supply in our country, cosmetics, dietary supplements, and products that emit radiation.
GPI	Generic Product Identifier
Managed Care Organization (MCO)	An entity that is organized for the purpose of providing medical care and is authorized as an insurer by the Insurance Commissioner of Puerto Rico, which contracts with ASES for the provision of Covered Services and Benefits throughout the Island based on PMPM Payments, under the PSG program.
MIP Fund Accounting System	MIP is today's leading accounting software for government and non-profit organizations nationwide. ASES Finance records corresponding in the Accounts Payable module.
NDC	National Drug Code
Non-Risk Payment Arrangement	Paying for services outside of the managed care capitation rates
Plan VITAL / Government Health Plan (PSG)	It is the health plan that the government of Puerto Rico grants through federal Medicaid and State funds.
Standard Operating Procedure (SOP)	A set of instructions that describes all relevant steps and activities of a process or procedure.

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Legal Base

Law 72 of September 7, 1995 created the Puerto Rico Health Insurance Administration (ASES) to, among its purposes, functions and powers, be the government agency in charge of implementing and managing medical plan services and contracting insurers to provide coverage for these services. One of the functions of the ASES is to identify profitable health service delivery models to meet the medical needs of the population insured by the Government Health Plan.

Background

A detail of the medications for SMA, Synthroid and Hepatitis C is presented where there is a description for:

SMA

The Spinal Muscular Atrophy population presents enormous challenges in terms due to the high costs involved for a population that has so far represented less than 20 patients. To ensure access to these therapies, a pre-authorization clinical protocol has been developed to guarantee the right treatment for the patients. Furthermore, a Non-Risk Payment Arrangement methodology has been utilized to meet the needs of this population without undermining the payment and cost of the actuarially quoted premiums.

This group of hereditary diseases progressively destroys motor neurons, producing weakness and wasting of skeletal muscles. The form of SMA can be classified into four types, depending on the motor milestone reached:

- Type I (Werdnig-Hoffman disease, childhood-onset SMA) is usually evident before the age of 6 months. Without treatment, affected children never sit or stand and usually die of respiratory failure before the age of 2 years.
- Type II usually presents the first symptoms between 6 and 18 months of age. Affected children can sit without support but cannot stand or walk without assistance and may have breathing difficulties. Life expectancy is shortened, but most people live into their teens or young adulthood.

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- Type III (Kugelberg-Welander disease) develops symptoms after 18 months of age and affects children who can walk independently. The disease manifests itself with difficulty walking, running, climbing stairs or getting up from a chair. Most people are prone to respiratory infections but can expect a normal life expectancy.
- Type IV symptoms develop after age 21, with mild to moderate muscle weakness and other symptoms.

Medications to be considered to treat this condition are:

- Spinraza (nusinersen) was approved by the US Food and Drug Administration (FDA) in December 2016 to treat children and adults with SMA Types II and III. The drug is injected into the fluid surrounding the spinal cord and increases production of the full-length survival motor neuron (SMN) protein that maintains the health of motor neurons. The benefits are better documented in infants and children, particularly when started early. (Attachment 1)
- Zolgensma (onasemnogene abeparvovec-xioi) is a gene therapy for children under 2 years of age with Type I SMA and was approved by the FDA in May 2019. It uses a "safe virus" to deliver a fully functional SMN gene to neurons target motor skills, which improves muscle development and function and increases survival. (Attachment 2)
- Evrysdi (Risdiplam oral sol 0.75 mg/ml) is an orally administered drug that was approved for type II and III patients two months of age and older in August 2020.

Synthroid

On June 14, 2017, ASES notified all Government Health Plan (GHP) beneficiaries about an update on the Synthroid medications management processed throughout the contracted GHP pharmacies. Any patient with prior utilization or new utilizers, where the prescribing physician indicates "do not substitute" for a generic or DAW¹ 1 code on the prescription, the pharmacy will dispense the brand name Synthroid. If the prescription does not specify DAW 1 or "no substitution" the pharmacy will fill the generic bioequivalent medication. Hence, if the claim is submitted with DAW 1 code, the contracted PBM adjudication system will not perform a look-back validation to determine whether it is appropriate or not to dispense either the brand or the generic product to the patient.

¹ Dispense as written.

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The instructions stated above are applicable to Synthroid only. Furthermore, no preauthorization will be needed for this product, and it will not be subject to an exception process. For the rest of the drugs, the PRHJA biogeneral rule will apply.

For this drug, the contracted PSG Health Entities will pay the Synthroid's generic price, while the ASBS will pay the difference in price between the generic drug and the brand name drug. The contracted Health Entities will be receiving a detailed Synthroid utilization report for their reference and for their internal reconciliation processes on each payment cycle.

Hepatitis C

Hepatitis C is an infectious disease caused by the hepatitis C virus (HCV). HCV is a single-stranded RNA virus of the Flaviviridae family. According to the Centers for Disease Control and Prevention (CDC), at least six distinct genotypes of the HCV virus and over 50 subtypes have been identified. Genotypes refer to genetic mutations found in the RNA strand that serve to identify the HCV strain. The different HCV genotypes and subtypes have different distributions throughout the world. Genotypes 1, 2 and 3 are distributed worldwide. Genotype 4 is most prevalent in the Middle East, Egypt, and central African countries. Genotype 5 is represented exclusively in Southern Africa, and genotype 6 in Southeast Asia. In the United States, genotype 1 accounts for almost 75% of those identified, the others being type 2 and 3.

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Purpose

The purpose of this SCP for the SMA medications, Synthroid and Hepatitis C medications is to establish and provide the guidelines to all the parties involved that carry out the automated data entry and certifications necessary for the execution of the claims payments for the medications mentioned previously to make sure PRHIA follows State and Federal regulations.

It is important to note that PRHIA will bear the risk 100 percent, as a result these products will not be included in the MCOs prime agreements.

SMA

The Puerto Rico Health Insurance Administration (PRHIA) will establish a Non-Risk Payment Arrangement payment process for SMA medications dispensed to the Vital Population Plan, effective as of January 1, 2023.

PRMJA will be the party responsible of paying for the utilization of SMA medications for all the HCPCS J Codes and NDCs associated to the GPs listed below. Please note that NDCs must be submitted on both pharmacy and non-pharmacy claims for rebates claiming purposes.



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GPI	NDC	GPI Name	Item Code	Brand Name
701050002020	Corresponding to the GPI NDCs have to be included on non-Pharmacy claims for rebates request purposes	Nusinersen Intrathecal Sol 12mg/5 ml	J2326 ²	Spinraza
74704050106416	Corresponding to the GPI NDCs have to be included on non-Pharmacy claims for rebates request purposes	Onasemnogene Abeparvovec Intav. Kit	J3399 ³	Zolgensma
74706560002120	Corresponding to the GPI NDCs have to be included on non-Pharmacy claims for rebates request purposes	Risdiplam Oral Sol 0.75 mg/ml	J8499 ⁴	Evrysdi

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² Injection, nusinersen, 0.3 mg

³ Injection, onasemnogene abeparvovec-xioi, per treatment up to 5x10¹⁵ vector genomes

⁴ Prescription drug, oral, non-chemotherapeutic, nec

NDC / I-CODES and GPIs must be reviewed and update by the MCOs when necessary to submit the active and correct code's.

DPS.

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The products listed above are necessary to treat the condition of SMA applicable under the Government Health Plan. ASES establishes a reimbursement procedure for the MCOs to address the referral services and to maintain the necessary documentation in an accurate and auditable manner.

Synthroid - Hepatitis C

The purpose of this procedure is to establish the guidelines for the certification of payments, completed the validation of claims for approved Synthroid and Hepatitis C drugs medications for beneficiaries of the Plan Vital and for any provider of the contracted Pharmacy network. In this way, documentation of the reimbursement processes to be audited is maintained.

Scope

This procedure establishes all necessary controls, notifications and disbursements related to the payment of claims for medications for SMA, Synthroid and Hepatitis C reported by the MCOs as established in the contract, are executed correctly and in compliance with all applicable State and Federal legislation.

Effective Date

SMA

January 1, 2023

Synthroid

The provisions of this Procedure come into force immediately after its approval.

Hepatitis C

The provisions of this Procedure come into force immediately after its approval.

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Responsible Parties

- ASES Office of Planning, Quality and Clinical Affairs.
- ASES Information System Office
- ASES Finance Office.
- MCOs contracted for Plan Vital

Procedures and Payments for Therapy Services

The claims and encounters to be evaluated by the Information System Office for this payment process will be those received as established in the contract for the MCOs, in *.CLM format - defined in layout "CARRIER to ASES see 4.1C_rev 20230221". This file is scheduled to be received on or before the 15th of each month. The Information System Office will carry out validations, where it identifies eligibility of the beneficiaries, according to the claims and encounters issued in the file, to complete the reimbursement as established in the MCOs, of Synthroid medications, hepatitis C and SMA coverage.

As part of its validation process, Information system will receive from the MCOs a supporting report of all the drugs and claims subject of this SOP on or before the 15th of each month. Once the validations have been completed the Information System Office, will generate reports and certifications in the Enterprise System (ES), sending it to the Finance Office for the reimbursement payment process to the MCOs as established in contracts for these medications.

The procedure to be followed to achieve the objective described above is as follows:

1) Validation for claim selection.

Using the ES database, claims will be selected with the following validation criteria:

- A. Carriers contracted for PSC (MAOs not included).
 - B. Services provided to eligible beneficiaries in the Plan Vital as of the date of service.
 - C. Unduplicated claims (MIP - Date of Service -from -to)
 - D. Claims Identified as Paid Date of service (from date) from the date established for each drug.
 - E. Claims Coding established for each drug (See Attachment XX)
- F. The *.CLM format - defined in layout "CARRIER to ASES see 4.1C_rev.20230221" will be deposited via STFP server in the folder defined for each MCO.

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In order so the MCOs receive the reimbursement of the drugs its necessary to submit all the information required by ASES for this purpose in special the NDC of each claim. No payment will be issued if the NDC number of the drug is missing.

1. The payment to be made will be the sum of the claims and drug encounter transactions that were completed through the validation process in the ASES ES system. The Finance Office will issue the payment for the amount presented in the certification generated by the ES Validation/Supplementary Payments system. Once Finance Office makes payment, it sends a summary to Information System Office to register the payment in the ES Validation System/Supplemental Payments and an email to each MCO of payment transfer.
2. This entry causes the automatic generation of a file with the details of the paid transactions which will be deposited in the SFTP Server. This file will be in *.xlsx format defined in the layout documents TAG "*Layour Outbound*" on each Module layout. (Attachment I)
3. Once the payment is completed in the Finance Office, the files with the transactions of the claims and drug encounters of the reimbursed payment will be deposited by Information System Office through the SFTP Server in the defined folder, for each MCO and in the Premium Payment/Receive from ASES. An email will be sent to the MCO's of the transfer of the files as appropriate.

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GRN	Nombre del medicamento	NDC	Habitat Code	Brand Name
747010500002020	Spiinrata Intrathecal Solution 12 MG/5ML	64406-0058-01	J2326	Spintraza
74706560002120	Evrtsdi Oral Solution Reconstituted 0.75 MG/ML	50242-0175-05	J8499	Evrtsdi
	Evrtsdi Oral Solution Reconstituted 0.75 MG/ML	50242-0175-07		
	Zolgensma 2.6-3.0 kg Intravenous Kit 2x8.3 ML	71894-0120-02		
	Zolgensma 3.1-3.5 kg Intravenous Kit 2x5.5ML & 1x8.3ML	71894-0121-03		
	Zolgensma 3.6-4.0 kg Intravenous Kit 1x5.5ML & 2x8.3ML	71894-0122-03		
	Zolgensma 4.1-4.5 kg Intravenous Kit 3x8.3 ML	71894-0123-03		
	Zolgensma 4.6-5.0 kg Intravenous Kit 2x5.5ML & 2x8.3ML	71894-0124-04		
747040501064**	Zolgensma 5.1-5.5 kg Intravenous Kit 1x5.5ML & 3x8.3ML	71894-0125-04		
	Zolgensma 5.6-6.0 kg Intravenous Kit 4x8.3 ML	71894-0126-04		
	Zolgensma 6.1-6.5 kg Intravenous Kit 2x5.5ML & 3x8.3ML	71894-0127-05		
	Zolgensma 6.6-7.0 kg Intravenous Kit 1x5.5ML & 4x8.3ML	71894-0128-05		
	Zolgensma 7.1-7.5 kg Intravenous Kit 5x8.3 ML	71894-0129-05		
	Zolgensma 7.6-8.0 kg Intravenous Kit 2x5.5ML & 4x8.3ML	71894-0130-06		
	Zolgensma 8.1-8.5 kg Intravenous Kit 1x5.5ML & 5x8.3ML	71894-0131-06		Zolgensma
	Zolgensma 8.6-9.0 kg Intravenous Kit 6x8.3 ML	71894-0132-06		
	Zolgensma 9.1-9.5 kg Intravenous Kit 2x5.5ML & 5x8.3ML	71894-0133-07		
	Zolgensma 9.6-10.0 kg Intravenous Kit 1x5.5ML & 6x8.3ML	71894-0134-07		
	Zolgensma 10.1-10.5 kg Intravenous Kit 7x8.3 ML	71894-0135-07		
747040501064**	Zolgensma 10.6-11.0 kg Intravenous Kit 2x5.5ML & 6x8.3ML	71894-0136-08		ADMINISTRACION DE SEGUROS DE SALUD
	Zolgensma 11.1-11.5 kg Intravenous Kit 1x5.5ML & 7x8.3ML	71894-0137-08		
	Zolgensma 11.6-12.0 kg Intravenous Kit 8x8.3 ML	71894-0138-08		
	Zolgensma 12.1-12.5 kg Intravenous Kit 2x5.5ML & 7x8.3ML	71894-0139-09		
	Zolgensma 12.6-13.0 kg Intravenous Kit 1x5.5ML & 8x8.3ML	71894-0140-09		
	Zolgensma 13.1-13.5 kg Intravenous Kit 9x8.3 ML	71894-0141-09		
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CLM FILE FIELDS TO IDENTIFY DATA REQUIREMENTS

#	Field	Name	Description	Desirable Data Format	Validator Notes	Prohibited to use this for billing	For claims validation purposes
7	bill_type	UB Type	Original bill type - Unbilled / Institutional HCFA/HCAS/1500 / Individual / Professional Pharmacy Claim D-Dental Claim	X	Required Must equal "U", "I", "P" or "D"	I	I, P
8	ub_bill_type	UB Type of Bill	Type of Bill on the UB claim form. The type of bill determines facility type, bill classification, and description.	XXX	Required for all claims submitted on Uniform Bill (UB) claim form. When present, must be one of the standard three digit codes as described in the National Uniform Billing Committee (NUBC) UB-04 data dictionary and manual.	012X, 013X, 083X, 085X	012X, 013X, 083X, 085X
36	proc_code	Procedure Code	For non-Pharmacy Standard procedure code conforming to HCPCS/CPT or HCSPN/CDT as appropriate	X(15)	For claims from CMS1500 / UB-04, when present must be a HCPCS/CPT code. For Dental claims must be a valid dental HCSPN/CDT code. For Pharmacy claims the must be all blanks.	3399	May be reported on other service lines for the claim for administration of a drug: 0251, 0230, 0231
43	mcn_code	Revenue Code	For UB-04 Claims NUBC Revenue Code	X(4)	Required for UB-04 claims. When present it must be a valid Revenue code. Must be zero filled to the left	026X, 0280, 0231	May be reported on other service lines for the claim for administration of a drug: 0251, 0230, 0231
47	lod_diag_01	Primary ICD Diagnosis code	Nurs-Pharmacy/Dental ICD diagnosis code.	X(8)	Not required for Pharmacy and Dental claims Must be a valid NDCDSM IV code without any decimal points. Diagnosis codes must be carried no higher than highest degree of detail. Left justified, blank filled.	612.0, 612.1, 612.8, 612.9	612.0, 612.1, 612.8, 612.9
48	lod_diag_12			X(15)	For claims from CMS1500 / UB-04, when present must be a HCPCS/CPT code. For Dental claims must be a valid dental HCSPN/CDT code. For Pharmacy claims the must be all blanks.	96365, 99218-99220, 99234-99236	May be reported on other service lines for the claim for administration of a drug: 9236, 99218-99220, 99234-99236
168	claim_type	Claim Type	Claim Type: - Inpatient - Outpatient - Professional	X	Required for all medical claims. For Rx and Dental claims, this field can be left blank.	I,O,P	I,O,P
1	center_id	Center ID	Center ID number National Drug Code (NDC) number prescribed drug in 5 & 2 format: NDC has to be submitted on all UB-04 service entries	X(21)	Must equal "I", "O" or "P" if not selected. Records need to be submitted by Year/Centers.	08, 10, 31, 12, 13	see tab [NDC Codes Shm] for related values
43	rx_ndc	National Drug Code		X(11)	NDC has to be submitted on all NDC on the claim		

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CLM FILE FIELDS to IDENTIFY SMA Spins

#	Field	Name	Description	Deliverable Data Format	Validation Rules	Providers were instructed to use this for Billing	For claims validation purposes
7	bill_type	Bill Type	Originalizing bill type – U=UB-04 / Institution / H=HCFCA/CMS1500 / Individual / Professional / Pharmacy Claim / Dental Claim	X	Required Must equal "U", "H", "P" or "D".	U	U, H or P
8	ub_bill_type	UB Type of Bill	Type of Bill on the UB claim form. The type of bill encodes facility type, bill classification, and description	XXX	Required for all claims submitted on Uniform Bill (UB) claim form. When present, must be one of the standard three digit codes as described in the National Uniform Billing Committee (NUBC) UB-04 data specifications manual	012X, 013X, 083X, 085X	012X, 013X, 083X, 085X
36	proc_code	Procedure Code	For non-pharmacy Standard procedure code conforming to HCPCS/ICPT or HCSPN/CDT as appropriate	X(15)	For claims from CMS1500 / UB-04, when present must be a HCPCS/ICPT code. For Dental claims must be a valid dental HCPCS/CDT code. For Pharmacy claims this must be all blanks.	J2326	J2326
43	rev_code	Revenue Code	For UB-04 Claims NUBC Revenue Code	X(4)	Required for UB-04 claims. When present it must be a valid Revenue code. Must be zero filled to the left.	049X	May be reported on other service lines for the claim for administration of a drug 049X
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47	lod_diag_01 to 58	Primary ICD Diagnosis code lod_diag_12	Non-Pharmacy/Dental ICD diagnosis code.	X(6)	Not required for Pharmacy and Dental claims. Must be a valid ICD/DSM IV code without any decimal points. Diagnosis codes must be carried to their highest degree of detail. Left justified, blank filled.	G12.0, G12.1, G12.8, G12.9	G12.0, G12.1, G12.8, G12.9	G12.0, G12.1, G12.8, G12.9
39	proto_code	Procedure Code	For non-Pharmacy Standard procedure code conforming to HCPCS/CPT or HCSPC/CDT as appropriate	X(15)	For claims from CMS1600 / UB-04, when present must be a HCPCS/CPT code. For Dental claims must be a valid dental HCPCS/CDT code. For Pharmacy claims this must be all blanks.	98450	MAY be reported on other service lines for the claim for administration of a drug: 98450	98450
100	claim_type	Claim Type	Claim Type: I=Inpatient O=Outpatient P=Professional	X	Required for all medical claims. For Rx and Dental claims, this field can be left blank. Must equal "I", "O" or "P" if populated.	O	I, O, P	O
1	carrier_id	Carrier ID	Carrier ID number	X(2)	Records must be submitted by Visit Carriers.	09,10,11,12,13	see tab [NDC Codes_SMA] for needed values	
43	nu_ndc	National Drug Code	National Drug Code value for prescribed drug in 5 4 2 format. NDC has to be submitted on all claims including medical.	X(11)	NDC has to be submitted, on all claims including medical; MCOs will have to require providers to submit NDC on the claim			

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CLM FILE FIELDS TO IDENTIFY SMA Entered

#	Field	Name	Description	Deliverable Data Format	Validation Rules	Providers were instructed to use these for claims validation purposes	For claims validation purposes
7	bill_type	Bill Type	Originating bill type – U=UB-04 / Institutional H=HCFA/CMS1500 / Individual / Professional P=Pharmacy Claim D=Dental Claim	X	Required Must equal "U", "H", "P" or "D".	U	U, H or P
8	ub_bill_type	UB Type of Bill	Type of Bill on the UB claim form. The type of bill encodes facility type, bill classification, and description.	XXX	Required for all claims submitted on Uniform Bill (UB) claim form. When present, must be one of the standard three digit codes as described in the National Uniform Billing Committee (NUBC) UB-04 data specifications manual.	012x, 013x, 083x, 085x	012x, 013x, 083x, 085x
36	proc_code	Procedure Code	For non-Pharmacy Standard procedure code conforming to HCPCS/CPT or HCSPC/CDT as appropriate	X(15)	For claims from CMS1500 / UB-04, when present must be a HCPCS/CPT code. For Dental claims must be a valid dental HCPCS/CDT code. For Pharmacy claims this must be all blanks.	J8499	J8499
43	rev_code	Revenue Code	For UB-04 Claims NUBC Revenue Code	X(4)	Required for UB-04 claims. When present it must be a valid Revenue code. Must be zero filled to the left.	049X	May be reported on other service lines for the claim administration of a drug: 049X
47	icd_diag_01_to_68	Primary ICD Diagnosis code	Non-Pharmacy/Dental ICD diagnosis code.	X(8)	Not required for Pharmacy and Dental claims. Must be a valid ICD/DSM IV code without any decimal points. Diagnosis codes must be carried to their highest degree of detail. Left justified, blank filled.	G12.0, G12.1, G12.8, G12.9	G12.0, G12.1, G12.8, G12.9

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36	proc_code	Procedure Code	For non-Pharmacy Standard procedure code conforming to HCPCS/CPT or HCSPC/CDT as appropriate	X(15)	For claims from CMS1500 / UB-04, when present must be a HCPCS/CPT code. For Dental claims must be a valid dental HCPCS/CDT code. For Pharmacy claims this must be all blanks.	96450	May be reported on other service lines for the claim for administration of a drug: 06450
108	claim_type	Claim Type	Claim Type: I=Inpatient O=Outpatient P=Professional	X	Required for all medical claims. For Rx and Dental claims, this field can be left blank. Must equal "I", "O" or "P" if populated.	W	I, O, P
1	carrier_ID	Carrier ID	Carrier ID number	X(2)	Records must be submitted by Vital Carriers.	09,10,11,12,13	
43	rx_ndc	National Drug Code	National Drug Code value for prescribed drug in 5 4 2 format. NDC has to be submitted on all claims including medical.	X(11)	NDC has to be submitted, on all claims including medical; MCOs will have to require providers to submit NDC on the claim		see tab [NDC Codes_SMA] for needed values



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