

ADDENDUM 9

Non-Risk Payment Arrangement – SMA,
Hepatitis C y Synthroid

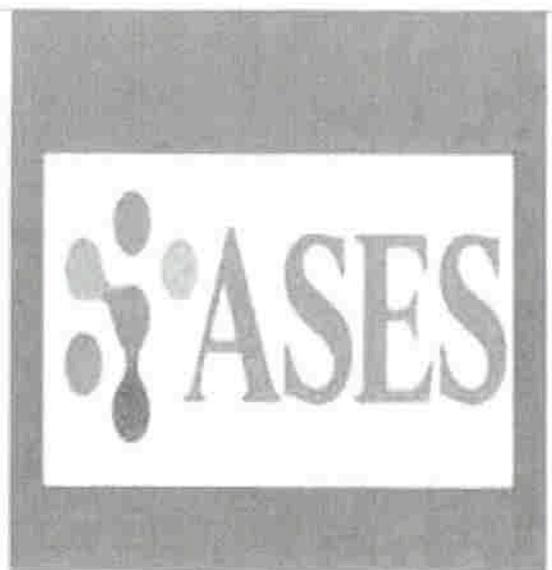
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Non-Risk
Payment
Arrangement for
Hepatitis C,
Synthroid and
SMA Medications

Standard Operating
Procedure

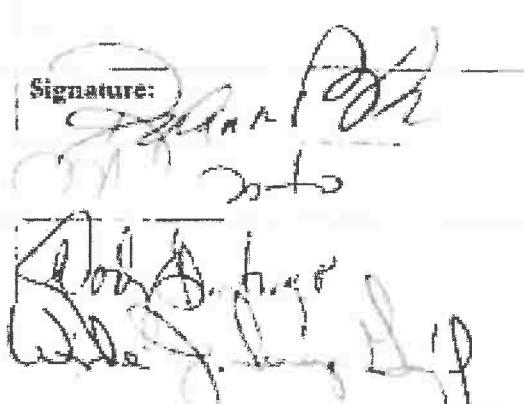
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General Information

Required Information	Description	Signature
Owner:	ASES	
Date:	7/01/2023	
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Document Revision History

Version number	Date	Description
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, 1993 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

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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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RPF

- 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)
- Zolgensima (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, ASBS 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.

PPG

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 PRHIA bioequivalent generic rule will apply.

For this drug, the contracted PSG Health Entities will pay the Synthroid's generic price, while the ASIS 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

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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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VDS

GPI	NDL	GPI Name	GPI	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	J2320 ²	Spinraza
74704050106416	Corresponding to the GPI NDCs have to be included on non-Pharmacy claims for rebates request purposes	Onasemnogene Abeeparvovec Lytic. Xioi 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	Evyrsdi

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¹ Inj/shot, nusinersen, 0.7 mg

² Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes

³ Prescription drug, oral, non-chemotherapeutic, not

NDC / ICD-9 and GPIs must be reviewed and update by the MCCs when necessary to submit the active and correct code's

DGF.

The products listed above are necessary to meet the condition of SMA applicable under the Government Health Plan. ASDES 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, heparins 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 is 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 PSG (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 to the MCOs receive the reimbursement of the drugs its necessary to submit all the information required by ASIES 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 ASIES 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 "Layout Outbound" on each Module layout. (Attachment 1)
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 ASIES. An email will be sent to the MCO's of the transfer of the files as appropriate.

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NDC Codes_SMA

GPI	Nombre del medicamento	NDC	Unidades	Nombre
74701050002020	Zolgensma 12 MG/5ML	64406-0058-01	12326	Spinraza
74705560002120	Evrysdi Oral Solution Reconstituted 0.75 MG/ML	50242-0175-05	18499	Evraysdi
	Evrysdi 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 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		
	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		
	ADMINISTRACION DE SEGUROS DE SALUD,	71894-0141-09		

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CMM FILE FIELDS TO IDENTIFY SMA ZIPPING

Field	Name	Description	Deliverable Data Format	Validation Rules	Provider's Name Instruction to use this for Billing	For claims validation purposes
7	bill_type	Billing bill type - U=UB-04 / Individual/ H=HCPCS/1500 / Individual/ Procedural/ P=Pharmacy Claim D=Detail Claim	X	Required Must enter "U", "H", "P" or "D"	U U, H, P	
8	ub_bill_type	UB Type of Bill		Required for all claims submitted on [Unicare Bill] (UB) claim form. When present, must be one of the standard three digit codes as specified in the National Uniform Billing Committee (NUBCH) UB-04 data standard version in use.	012X, 013X, 033X, 055X 012X, 013X, 033X, 055X	
16	proc_code	Procedure Code		Required for claims from CMS1500 / UB-04, when present must be a HCPCS/CPT code For Dental claims must be a valid dental HCPCSGCD1 code. For Pharmacy claims this must be all blanks.	13395 13395	May be reported on other service lines for the claim for administration of a drug: 0284, 0230, 0231
43	rev_code	Revenue Code		Required for UB-04 claims, When present it must be a valid Revenue code Must be zero filled to the left	026X, 0250, 0231	
47	cd_ding_01 to to 58	Primary ICD Diagnosis code ICD diag_17	X(1)	Not required for Pharmacy and Dental claims Must be a valid CDX5M IV code without any decimal points. Diagnosis codes must be carried to their highest degree of detail. Left justified blank field.	G12.0, G12.1, G12.8, G12.9 G12.0, G12.1, G12.8, G12.9	G12.0, G12.1, G12.8, G12.9 G12.0, G12.1, G12.8, G12.9
36	proc_code	Procedure Code	X(10)	For non-Pharmacy claims procedure code conforming to HCPCS/CPT or HCPCSGCD1 as appropriate	96365, 99218-99220, 99234-99236	May be reported on other service lines for the claim for administration of a drug: 0284, 99236-99238, 99236-99239
108	claim_type	Claim Type	X	Claim Type: I=Inpatient O=Outpatient P=Professional	I/O I, O, P	
1	carrier_id	Carrier ID	X(21)	Must be just "I" or "P" if professional Records must be submitted by Mail Carriers.		08, 10, *11, 12, 13
43	nrc_ndc	National Drug Code	X(11)	NDC has to be submitted, on all claims including medical; NDC will have to require providers to submit NDC on this claim if claim is medical claim		see lab [NDC Codes_Ship] for related values

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CMS FILE FIELDS to IDENTIFY SMA Splitrate

#	Field	Name	Description	Deliverable Date Format	Validation Rules	Providers were instructed to use this for billing	For claims validation purposes
7	bill_type	Bill Type	Originating bill type – U=UB-04 / Institutional H=HCFA/CMS-1500 / Individual 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 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 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	icd_diag_01 to 50	Primary ICD Diagnosis code	Non-Pharmacy/Dental ICD diagnosis codes.	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	
36	proc_code	Procedure Code	For non-Pharmacy Standard procedure code conforming to HCPCS/CPT or HCSPN/CPT 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. 96450
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.	109,110,111,12,13	
43	rx_ndc	National Drug Code	National Drug Code value for prescribed drug in 5 & 2 format. NDC has to be submitted on all claims including medical.	X(11)	NDC has to be submitted, on all claims including medical; MCCOs will have to require providers to submit NDC on the claim		see tab [NDC Codes_SMA] for needed values

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CLM FILE FIELDS* TO IDENTIFY SMA Entysdi

Field	Name	Description	Deliverable Data Format	Validation Rules	Providers Were Instructed to use these for billing purposes	For claims validation purposes
7	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 conforming to HCPCS/ICPT or HCSPC/ICDT as appropriate	X(15)	For non-Pharmacy Standard procedure code conforming to HCPCS/ICPT or HCSPC/ICDT as appropriate	18499	18499
43	rev_code	Revenue Code	X(4)	For UB-04 Claims NUBC Revenue Code	049X	May be reported on other service lines for the claim for administration of a drug: 049X
47 to 68	lcd_diag_D1 to lcd_diag_12	Primary 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 HCSPIC/CDT as appropriate	X[16)	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.	96450	May be reported on other service lines for the claim for administration of a drug: 96450
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.	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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