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Changes in Drug Rebate Manufacturers

The following changes are being made in manufacturers with Drug Rebate Agreements. They are listed by manufacturer code, which are the first five digits of the NDC.

Additions

The following labelers have entered into Drug Rebate Agreements and joined the rebate program effective on the dates indicated below:

Code	<u>Manufacturer</u>	<u>Date</u>
50907	FEI Women's Health LLC	09/29/2004
60242	Neil Laboratories, Inc.	07/01/2004
66378	Presutti Laboratories, Inc.	07/13/2004
68084	American Health Packaging	06/02/2004
68094	Precision Dose, Inc	06/14/2004
68135	Biomarin Pharmaceuticals	05/24/2004
68188	Alliant Pharmaceuticals	06/04/2004
68712	JSJ Pharmaceuticals	07/14/2004
68782	Eyetech Pharmaceuticals	07/29/2004

Terminated Labelers

The following labeler code was voluntarily terminated effective **July 1, 2004** Foxmeyer Drug Company (Health Mart) (Labeler Code 52297).

The following labeler code was terminated effective **July 1, 2004**: RSJ, Inc. (Western Research Laboratories) (Labeler Code 64727).

The following labeler code is being voluntarily terminated effective **October 1, 2004**: Radford (Labeler Code 63252).

The following labeler codes were terminated effective October 1, 2004:

C O Truxton, Inc. (Labeler Code 00463);

BD Becton Dickinson (Labeler Code 08290);

Select Brand Distributors (Labeler Code 15127):

Penederm, Inc. (Labeler Code 25074);

Creighton Products Corp. (Labeler Code 50752);

Excelsior Medical Corp (Labeler Code 63807); and

D&K Healthcare Resources (Labeler Code 65759):

Reinstated Labelers

Neil Laboratories, Inc. labeler code 60242, has signed a new rebate agreement and was reinstated in the drug rebate program effective July 1, 2004.

Clinical Policy and Programs

The Division of Medical Assistance (DMA) has changed the name of the Medical Policy Section to the Clinical Policy and Programs Section. This new title more accurately reflects the various clinical specialties within DMA's program policy area.

The mission of the Clinical Policy and Programs Section is to structure benefits available to Medicaid clients in a manner that promotes access to medically necessary and cost effective care. This section is responsible for:

- Behavioral Health Services
- Clinical Policy Development and Technical Support
- Community Alternatives Program Services
- Dental Services
- Facility and Community Care Services
- Pharmacy and Ancillary Services
- Practitioner and Clinic Services

Along with the new title comes a change in the section's leadership. Marcia Rao joins DMA as the Assistant Director for Clinical Policy and Programs. Ms. Rao brings with her a wealth of knowledge and experience as she has worked in broad areas of medical policy for the Medicaid program in the State of New York for more than twenty years. She has worked in systems design, overseen the State Plan, and developed and implemented many programs, including waivers. She has particular interest in community care and in children's needs.

Medicare Crossovers

On September 6, 2004, the N.C. Medicaid program returned to processing all crossover claims billed on a CMS-1500 form or as an 837 professional transaction as direct crossovers from Medicare.

Pharmacy providers should continue to handle Medicare crossover claims by billing Medicare first for the pharmaceutical products covered by that program. If Medicare reimbursement does not equal 100% of the Medicaid allowable rate, the pharmacy provider may then bill the remaining amount due as a Pharmacy Claim. The preferred method of billing these claims is POS, although it may be necessary to bill using either paper or batch.

A copay should not be collected on any of the claims billed to Medicare. Once Medicare has paid, bill Medicaid for the remaining amount. The system will not deduct a copay for crossover claims.

Overriding Copay with Pregnancy Diagnosis Codes

Pregnancy is one of the listed reasons for exemption from copay. If the recipient has a pink card, the system will automatically take this into account. If a recipient has a blue card, the pharmacist will need to indicate that the recipient is pregnant. A '4' in the Prior Auth Field on a point-of-sale (POS) claim, '2' in the pregnancy indicator field for POS, or a "P" in the Location Field for a batch/manual claim indicates an exemption from the copayment deduction for pregnancy. The POS system will also now accept the ICD9 codes for pregnancy in the diagnosis field (V22-V23) to exempt copay.

Removal of ADHD Drugs, Rebetron and Smoking Cessation Products from the Prior Authorization Drug List

Effective August 5, 2004, the following drugs will no longer require prior authorization from Medicaid:

Amphetamine Mixtures (Adderall, Adderall XR)

Dextroamphetamine (generics, Dexadrine, Dextrostat)

Methamphetamine (Desoxyn)

Methylphenidate (generics, Ritalin, Methylin, Concerta)

Methylphenidate sustained-release (generics, Ritalin SR, Ritalin LA, Methylin ER, Metadate ER, Methadate CD, Ritalin LA 20mg, 30mg,40mg)

Pemoline (generics, Cylert, PemADD)

Focalin (Dexmethylphenidate HCL)

Rebetron (Interferon Alfa-2b and Ribavirin combination pack)

Synagis/Respigam

Effective August 25, 2004, the following Smoking Cessation Drugs will no longer require prior authorization from Medicaid:

Zyban (Buproprion) Nicotine Patch, Nicotrol NS Nicotrol Cartridge Inhaler

New Prior Authorization Criteria for Oxycontin

Effective August 24, 2004, the North Carolina Prior Authorization criteria for Oxycontin changed to include the following items:

Criteria for Cancer or Patients with Other Terminal Illnesses

- 1. Patient must have failed therapy with generic products (oxycodone or similar narcotic analgesics).
- 2. A maximum of 6 tablets per day may be authorized.
- 3. Length of therapy may be approved for up to one year.

Criteria for Chronic, Nonmalignant Pain

- 1. Patient must have failed therapy with generic products (oxycodone or similar narcotic analgesics).
- 2. Patient must have a diagnosis of chronic pain syndrome of at least four weeks duration.
- 3. Patient must have a pain agreement on file at the physician's office.
- 4. A copy of this form may be requested by DMA.
- 5. A maximum of 4 tablets per day may be authorized.
- 6. Length of therapy may be approved for up to one year.

References

Management of Chronic Non-Malignant Pain _ Position statement of the NC Board of Medical Board. http://www.ncmedboard.org/mgmt.htm

Synagis Coverage for 2004-2005

For the Synagis season 2004-2005, Synagis will no longer require prior authorization. However, physicians are required to complete a Synagis for RSV Prophylaxis criteria (1, 2, or 3) form of coverage. These forms will be available on the Division of Medical Assistance's website at http://www.dhhs.state.nc.us/dma/forms.html by September 15, 2004. The responsibility for appropriate usage for both Synagis and Respigam will be placed on prescribers and pharmacy providers. Prior Authorization may be resumed at any time if the Division suspects inappropriate drug utilization. The North Carolina Physicians Advisory Group (NCPAG) has met with specialists in the state and members of the Pediatric Red Book committee to develop three Synagis usage criteria forms. Please ensure that the person completing the forms has verified that the conditions exist and are accurate. If a patient does not fit the criteria explicitly for categories 1, 2 or 3, the prescriber can request an exemption for Synagis, by submitting the "Request for Medical Review for Synagis Outside of Criteria" form and faxing the request to DMA at 919-715-1255.

Completed forms should be sent to the physician's pharmacy provider of choice for processing. If clinical criteria, 1, 2, or 3 applies, then the pharmacy provider reviews the form to ensure that it has been completed in full and verifies the recipients Medicaid eligibility. The pharmacy provider ships the Synagis to the physicians office.

In the event that a recipient does not meet the clinical criteria for coverage, the physician can request an exemption by completing a N.C. Medicaid Request for Medical Review for Synagis Outside of Criteria form and submitting it to the pharmacy provider. The pharmacy provider forwards the form to DMA for clinical review. If the request for coverage is denied, the physician may appeal to DMA.

Physicians and pharmacy providers are subject to audits of Synagis records by the DMA Program Integrity Unit. All Synagis criteria forms and requests for coverage outside of criteria must be sent by the pharmacy provider on a weekly basis to DMA for review.

The start of the Synagis season will be October 15, 2004. No more than 5 monthly doses of Synagis or RespiGam can be obtained by using these forms. The number of doses should be adjusted if an infant received the first dose prior to a hospital discharge. Delays in getting a request processed can occur if the patient does not have a Medicaid ID number or the form is not complete. The forms must be signed by the prescriber and submitted to the pharmacy distributor of choice. They may be handwritten or filled out electronically.

Please refer to the following guidelines when submitting a request:

<u>Criteria 1a through 1d</u> – Infants (24 months or younger) with CLD (Chronic Lung Disease), CF (Cystic Fibrosis), CHD (Congenital Heart Disease), or Severe Immunodeficiency

<u>Criteria 2a and 2b</u> – Infants born at 32 weeks, 0 days gestation or earlier without CLD

Once a child qualifies for initiation of prophylaxis at the start of the RSV season, administration should continue throughout the season and not stop at the point that the infant reaches 6 or 12 months of age.

Criteria 3 - Infants Born at 32 Weeks, 1 day - 35 Weeks, 0 day Gestation without CLD

High-risk infants should be kept away from crowds and from situations in which exposure to infected individuals cannot be controlled. Participation in child care should be restricted during the RSV season for high-risk infants whenever feasible.

Request for Medical Review for Synagis Outside of Criteria

This form will be used for patients who do not explicitly meet criteria 1, 2 or 3, whose providers still wish to prescribe Synagis. Please fill out the requested information, and fax to DMA at 919-715-1255.

Addition To The Prior Authorization Criteria Form Under Provigil

Effective August 24, 2004 the Prior Authorization process for Provigil will require additional criteria which is indicated below.

Criteria:

Approval of modafinil will be considered as treatment to improve wakefulness for patients who:

- Are at least 16 years old and have a diagnosis of narcolepsy.
- Are at least 16 years old and have excessive sleepiness associated with shift work sleep disorder.
- Require adjunct treatment for a diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS) with concurrent use of continuous positive airway pressure (CPAP) if CPAP is the treatment of choice.
- The maximum daily dose should be 2 tablets per day for all strengths.

References:

1. Prescriber Information - PROVIGIL® (pro-vij-el) Tablets [C-IV] - Generic name: modafinil. Cephalon, Inc. West Chester, PA 19380. February 2004.

Technical Correction to General Policy for Over the Counter Medications

A technical correction to clarify how over the counter medications are dispensed was made to Section 1.0 of General Coverage Policy #A2, *Over the Counter Medications*. The updated policy is now available on DMA's website at http://www.dhhs.state.nc.us/dma/mp/mpindex.htm.

Legislative Mandate to Remove Anorexia, Weight Loss, Weight Gain Products from Coverage

Legislation was passed July 1, 2004 removing anorexia, weight loss and weight gain products from the NC Medicaid Pharmacy Program. On September 28, 2004, all weight loss products were end-dated to non-coverage status, with an effective date of July 1, 2004 (claims previously paid will not be recouped). NC Medicaid will deny claims for weight loss drugs: (J8A - Anorexic Agents, D5A - Fat Absorption Decreasing Agents) including Meridia, and Xenical.

NCPDP 3.2

On October 15, 2003, HIPAA mandated that all pharmacy transactions be submitted using NCPDP 5.1. North Carolina has continued to accept claims submitted via 3.2 to give providers additional time to make the conversion. Effective January 1, 2005, NCPDP 3.2 will no longer be supported.

Coordination of Benefits (Third Party Cost Avoidance)

The North Carolina Medicaid Program began cost avoiding pharmacy claims for patients who have other coverage for prescription drugs on June 29, 2004. The pharmacy will receive a denial through the Point of Sale (POS) system that the other third party should be billed as the primary payer. Medicaid can then be billed as a secondary payer.

The POS (Point of Sale) will check for current third party coverage on the eligibility file. A message will be sent back by the POS system telling the provider that the recipient has third party coverage for that date of service. If other coverage is indicated, the number '99' must be entered in field 338-5C. When a claim is denied for other coverage, the POS system will deny the claim and will send the third party information that is currently indicated on the eligibility file. The message will appear in the following format:

PBM or INS name/Payer phone number/BIN number/Policy #/ RX group number

(Note: Will only display information currently available on the recipient eligibility file. The BIN will be listed if it can be identified).

Pregnant Woman Are Exempt

For recipients with MPW coverage (pink Medicaid identification card), the eligibility file automatically exempts the claim from the cost avoidance process.

With the Blue Medicaid Card, the Pharmacist can indicate pregnancy in one of two ways:

- (1) Indicate the diagnosis of V22.2, (V22 V23 are now included) in the diagnosis field on the POS transaction or
- (2) Use the 5.1 "Pregnancy Indicator" field in the Patient Segment. A value of '2' will be used to indicate this override

<u>Override Codes for Cost Avoidance Process</u> Claim Segment defined as 308-C8 (Other Coverage Code)

01= No Other Coverage Identified

- **02** = Other Coverage Exists Payment Collected (The member has other coverage and the payer has returned a payment amount. The payment amount is submitted in field 431-DV to the secondary payer (e.g.: Medicaid). This override code should only be used if other coverage is indicated.
- **03 = Other Coverage Exists This Claim Not Covered** (Claim not covered under primary Third Party Plan. If primary denied the claim as Refill Too Soon, the claim would be submitted to the secondary payer with the Other Coverage Code 3. In this situation, claim would more than likely be too early for Medicaid as well.)
- **04 = Other Coverage Exists Payment Not Collected** (Used when the member has other coverage and that payer has accepted the claim, but did not return any payment. This would be an example in which the member had a deductible amount to meet under the primary payer. The member is responsible for 100% of the payment, and the payer returns 100% of the payment, and the payer returns \$0.)
- 07 = Other Coverage Exists- Not in Effect at Time of Service (Other coverage exists but not on date of service.)

The override codes listed above will be reported back to Medicaid on a monthly basis.

Example: After Third Party insurer has paid, the claim can be billed to Medicaid with the other coverage amount indicated. For example, if a \$100.00 claim is billed to PCS and they pay \$65.00 (the patient has a \$20.00 copay), the claim is then submitted to Medicaid with \$100.00 billed amount and \$65.00 in the other coverage field (431-DV). The system will calculate the Medicaid allowable and then subtract \$65.00 from that amount. There should not be a reference to the \$20.00 copay.

Pharmacy claims that are submitted via batch or paper will also be subject to the coordination of benefits edit. If a paper claim is denied for third party and the patient indicates they have no other coverage, the edit can be overridden in the same manner as the Medicare cost avoidance edit (place an 'O' in the family planning field).

Vioxx® Voluntary Recall and NC Medicaid Coverage

Merck & Co., Inc. announced a voluntary withdrawal of Vioxx® (rofecoxib) from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events (including heart attack and stroke) in patients on Vioxx®.

On October 1, 2004, N.C. Medicaid end dated all forms of Vioxx® and will no longer cover any strength or package size. There will be no PA overrides made available for this drug. Individual prescribers must decide whether their patients currently taking Vioxx® should utilize another Cox-2, or change to another anti-inflammatory agent.

The New NCMMIS Commitment to North Carolina Providers

On July 1, 2004, Carmen Hooker Odom, Secretary of the Department of Health and Human Services, created the Office of Medicaid Management Information System (MMIS) Services to ensure a successful transition to the new NCLeads system. The Office of MMIS Services reports directly to the Office of the Secretary and will work with Affiliated Computer Services (ACS) State Healthcare LLC on the implementation of the new NCLeads system. Staff from the Division of Medical Assistance; the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services have been reassigned to the Office of MMIS Services to assist with the transition.

The Office of MMIS Services Provider Relations Team is developing a website for providers to access information about NCLeads system and for updates about the transition to the new system. Providers will be notified through the general Medicaid bulletin when the website is available.

Providers may contact the Provider Relations Team with questions or comments by calling 919-855-3112 or by email at ncmail.net.

Federal Mac List Changes

Effective October 28, 2004, the following changes were made to the Medicaid Drug Federal Upper Limit List:

Ful Deletions Generic Name

Betamethasone Valerate

EQ 0.1% Base, Lotion, Topical, 60 ml

Chlorpheniramine Maleate

4 mg, Tablet, Oral, 100

Homatropine Methylbromide; Hydrocodone Bitartrate

1.5 mg/5 ml; 5 mg/5 ml, Syrup, Oral, 480 ml

Isosorbide Dinitrate

2.5 mg, Tablet, Sublingual, 100

Ketoprofen

50 mg, Capsule, Oral, 100

75 mg, Capsule, Oral, 100

Triamcinolone Acetonide

0.025%, Cream, Topical, 80 gm

FUL Additions

Generic Name Dextroamphetamine Sulfate	
10 mg, Tablet, Oral, 100	\$0.3435 B
Flecainide Acetate 50 mg, Tablet, Oral, 100 100 mg, Tablet, Oral, 100 150 mg, Tablet, Oral, 100	\$0.8610 B \$1.4070 B \$1.9328 B
Fluocinonide Emulsified Base (Fluocinonide-E) 0.05%, Cream, Topical, 60 gm	\$0.2453 R
Lithium Carbonate 300 mg, Capsule, Oral, 1000	\$0.1350 B
Metformin Hydrochloride 1000 mg, Tablet, Oral, 100	\$0.4597 B
Mirtazapine 15 mg, Tablet, Oral, 30 30 mg, Tablet, Oral, 30 45 mg, Tablet, Oral, 30	\$1.6300 B \$1.6775 B \$1.7100 B
Pergolide Mesylate 1 mg, Tablet, Oral, 100	\$3.4872 R
Rimantadine Hydrochloride 100 mg, Tablet, Oral, 100	\$1.5120 B

FUL Additions (cont.)

Generic Name	FUL Price
Tamoxifen Citrate	
10 mg, Tablet, Oral, 60	\$0.9713 B
20 mg, Tablet, Oral, 30	\$1.9425 B

FUL Price Decreases

Generic Name	FUL Price
Acetaminophen; Hydrocodone Bitartrate 500 mg; 5 mg, Tablet, Oral, 100	\$0.0833 B
Atropine Sulfate; Diphenoxylate Hydrochloride 0.025 mg; 2.5 mg, Tablet, Oral, 100	\$0.1088 B
Captopril 12.5, mg, Tablet, Oral, 100 50 mg, Tablet, Oral, 100 100 mg, Tablet, Oral, 100	\$0.0232 B \$0.0390 B \$0.1080 B
Cefaclor EQ 125 mg Base/5 ml, Powder for Reconstitution, Oral, 150 EQ 187 mg Base/5 ml, Powder for Reconstitution, Oral, 100	\$0.0980 B \$0.1470 B
Chlorhexidine Gluconate 0.12%, Solution, Dental, 480 ml	\$0.0109 B
Chlorzoxazone 500 mg, Tablet, Oral, 100	\$0.0757 B
Cimetidine 400 mg, Tablet, Oral, 100 Diazepam	\$0.1071 R
10 mg, Tablet, Oral, 100 Famotidine	\$0.0573 B
20 mg, Tablet, Oral, 100 40 mg, Tablet, Oral, 100	\$0.1500 B \$0.3000 B
Fluocinonide 0.05%, Cream, Topical, 60 gm	\$0.0790 R
Flurbiprofen 100 mg, Tablet, Oral, 100	\$0.2438 B
Gentamicin Sulfate EQ 0.3% Base, Solution/Drops, Ophthalmic, 5 ml	\$0.5700 B
Gramicidin; Neomycin Sulfate; Polymyxin B Sulfate 0.025 mg/ml; EQ 1.75 mg Base/ml; 10,000 units/ml, Solution/Drops, Ophthalmic, 10 ml	\$2.0250 B
Haloperidol Lactate EQ 2 mg/ml, Concentrate, Oral, 120 ml	\$0.1369 B
Hydrochlorothiazide; Triamterene 25 mg; 37.5 mg, Tablet, Oral, 100	\$0.1683 R

FUL Price Decreases (cont.)

Generic Name Meclizine Hydrochloride 25 mg, Tablet, Oral, 100	FUL Price \$0.0420 B
Metoprolol Tartrate 100 mg, Tablet, Oral, 100	\$0.0690 B
Oxazepam 15 mg, Capsule, Oral, 100	\$0.5709 B
Sulfamethoxazole; Trimethoprim 800 mg; 16 mg, Tablet, Oral, 100	\$0.1454 R
Ticlopidine Hydrochloride 250 mg, Tablet, Oral, 60	\$0.2732 B
Tizanidine Hydrochloride 2 mg, Tablet, Oral, 150 4 mg, Tablet, Oral, 150	\$0.6499 B \$0.7899 B
Tobramycin 0.3%, Solution/Drops, Ophthalmic, 5 ml	\$0.6720 B
Verapamil Hydrochloride 40 mg, Tablet, Oral, 100	\$0.1509 B
FUL Price Increases	
Generic Name Acetaminophen; Butalbital; Caffeine 500 mg; 50 mg; 40 mg, Tablet, Oral, 100	FUL Price \$0.6870 B
Acetaminophen; Codeine Phosphate 300 mg; 60 mg, Tablet, Oral, 100	\$0.3833 B
Acetaminophen; Oxycodone Hydrochloride 500 mg; 5 mg, Capsule, Oral, 100	\$0.2248 B
Amoxicillin 250 mg, Capsule, Oral, 100 500 mg, Capsule, Oral, 100	\$0.0675 B \$0.1302 R
Atenolol 50 mg, Tablet, Oral, 100 100 mg, Tablet, Oral, 100	\$0.1058 B \$0.1943 B
Betamethasone Dipropionate EQ 0.05% Base, Lotion, Topical, 60 ml	\$0.1500 B
Bisoprolol Fumarate; Hydrochlorothiazide 2.5 mg; 6.25 mg, Tablet, Oral, 100 5 mg; 6.25 mg, Tablet, Oral, 100	\$1.0260 B \$1.0260 B

FUL Price Increases (cont.)

Generic Name Brompheniramine Maleate; Dextromethorphan Hydrobromide; Pseudoephedrine Hydrochloride	FUL Price
2 mg/10mg/30mg per 5 ml, Syrup, Oral, 480 ml	\$0.0387 B
Cimetidine 200 mg, Tablet, Oral, 100	\$0.1313 B
Clomipramine Hydrochloride 75 mg, Capsule, Oral, 100	\$0.6623 B
Doxycycline Hyclate EQ 50 mg Base, Capsule, Oral, 50	\$0.1317 B
Enalapril Maleate 2.5 mg, Tablet, Oral, 100	\$0.4334 B
Erythromycin 0.5%, Ointment, Ophthalmic, 3 gm	\$1.0714 B
Estradiol 1 mg, Tablet, Oral, 100	\$0.2175 B
Glipizide 10 mg, Tablet, Oral, 100	\$0.1192 B
Hydrocortisone 0.05%, Cream, Topical, 30 gm	\$0.0510 M
Lidocaine Hydrochloride 2%, Solution, Oral, 100 ml	\$0.0315 R
Potassium Chloride 8 MEQ, Tablet, Extended Release, Oral, 100	\$0.0893 B
Triamcinolone Acetonide 0.1%, Cream, Topical, 80 gm	\$0.0469 B

Timolol Maleate – FUL Clarification

Timolol Maleate 0.5% Ophthalmic Solution currently has a FUL of \$0.9000. It has recently come to the attention of CMS that Ista Pharmaceuticals has received FDA-approval for Istalol, which is their version of Timolol Maleate 0.5% Ophthalmic Solution. The FDA has determined that Istalol is not therapeutically equivalent to the other versions of Timolol Maleate 0.5% Ophthalmic Solution that are currently on the market. Therefore, the FUL of \$0.9000 does not apply to Istalol. However, the FUL does continue to apply to all other versions of Timolol Maleate 0.5% Ophthalmic Solution

Checkwrite Schedule

October 5, 2004	November 2, 2004	December 7, 2004
October 12, 2004	November 9, 2004	December 14, 2004
October 19, 2004	November 16, 2004	December 22, 2004
	November 24, 2004	

Electronic Cut-Off Schedule

October 1, 2004	October 29, 2004	December 3, 2004
October 8, 2004	November 5, 2004	December 10, 2004
October 15, 2004	November 12, 2004	December 17, 2004
	November 19, 2004	

Electronic claims must be transmitted and completed by 5:00 p.m. on the cut-off date to be included in the next checkwrite. Any claims transmitted after 5:00 p.m. will be processed on the second checkwrite following the transmission date. POS claims must be transmitted and completed by 12:00 midnight on the day prior to the electronic cut-off date to be included in the next checkwrite.

Gary H. Fuquay, Director

Division of Medical Assistance

Department of Health and Human Services

Cheryll Collier Executive Director

EDS

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