

MAYZENT® Prescription Start Form



FAX
1-877-750-9068

ENROLL ONLINE
CoverMyMeds.com

QUESTIONS? CALL
1-877-MAYZENT (1-877-629-9368)

New Patient Restarting Treatment Existing Patient

1. PATIENT INFORMATION

Cannot process form without this field completed

First Name	Middle Initial	Last Name
Sex: M F Other	Date of Birth (MM/DD/YYYY)	
Address (no PO boxes)		
City	State	ZIP
Phone number	Home	Cell

E-mail (To make more communications convenient and paperless)

Contact Preferences **Preferred Language**
OK to leave MAYZENT voicemail English Spanish
Other _____

Caregiver Information

Name of Caregiver (First & Last) Caregiver Phone
Caregiver E-mail

Insurance Information No insurance
(include a copy of both sides of all cards, including secondary insurance)

Medical Insurance(s)

Cardholder Name(s)
Insurance Carrier(s) Phone Number(s)
Cardholder ID Number(s) Group Number(s)
Secondary Medical Insurance Carrier

Prescription Insurance

Cardholder Name
Prescription Insurance Carrier Phone Number
ID Number Group Number
PCN Number BIN Number

2. PATIENT AUTHORIZATIONS AND ADDITIONAL CONSENTS

Cannot process form without this field completed

I have read and agree to the Patient Authorization, which includes sharing of genetic information (page 3)

→ X

Patient/Legal Guardian Signature

Date of Signature (MM/DD/YYYY)

MAYZENT Co-pay Program: I have read and agree to the Terms and Conditions for participation (please see page 4)
Receiving text messages and calls: I have read and agree to receiving marketing texts and calls as explained in the Telephone Consumer Protection Act (TCPA) Consent (optional, please see page 3)
I have read and agree to the Fair Credit Reporting Act (FCRA) Authorization (optional, please see page 4)

FOR OFFICE USE ONLY

3. PRESCRIBING PHYSICIAN INFORMATION

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First Name Last Name
Address
City State ZIP

Phone Fax
NPI #
Office Contact Name Office Contact Phone
E-mail Address

4. SUPPORT SERVICES

Request Co-pay Support Only: Select checkbox to skip remaining Section 4 if the MAYZENT prescription will be sent directly to the Specialty Pharmacy and assessments are not needed.

Assessments have been completed and I clear for therapy: The following tests are completed or not required for this patient: CBC, LFTs (transaminase & bilirubin), VZV antibody serology, genotype CYP2C9 (to determine dose),* ECG, and a macular edema screening.†

Assessments are still needed and I do not clear patient for therapy: The following tests are required and not obtainable through Alongside™ MAYZENT: CBC, LFTs (transaminase & bilirubin), VZV antibody serology, genotype CYP2C9 (to determine dose), ECG, and a macular edema screening.

OR

First-Dose Observation (FDO) period:
(select 1)

FDO not required for patient†
FDO required for patient† outside of the support program
FDO Date: _____

Ship treatment initiation product for FDO to:

Prescribing office FDO location below:
Health Care Provider
Office Contact Phone
Address
City State ZIP

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5. PRESCRIPTION INFORMATION

A DOSE IS REQUIRED TO INITIATE COVERAGE SUPPORT. PRODUCT WILL NOT BE DISPENSED UNTIL YOU HAVE CLEARED THE PATIENT FOR THERAPY.

The recommended maintenance dose is 2 mg^s taken orally once daily. **You will be required to confirm or change the patient's dose before dispense.**

Cannot process form without this field completed

Patient information:

Name (First & Last)

Date of Birth (MM/DD/YYYY)

Primary diagnosis: (select 1)

ICD-10:G35

Other: _____

Active SPMS

CIS/RRMS

Preferred Specialty Pharmacy:

No preference Onsite dispense

Specialty Pharmacy

Phone

Fax

Additional Notes:

Pharmacy Prescription:

For **2-mg** maintenance dose patients:

MAYZENT (siponimod) tablets

0.25-mg tablet - Starter Pack.....NDC 0078-0979-12

2-mg tablet, Bottle of 30 tablets.....NDC 0078-0986-15

2-mg Starter Pack:

No, patient already on therapy

Yes, 0.25-mg Starter Pack

SIG: twelve 0.25-mg tablets for a 5-day supply

Day 1: 1 x 0.25 mg **Day 4:** 3 x 0.25 mg

Day 2: 1 x 0.25 mg **Day 5:** 5 x 0.25 mg

Day 3: 2 x 0.25 mg

Qty: 1 Starter Pack, then 1 refill

Maintenance Dose:

2-mg tablet

SIG: 1 tablet taken orally once a day

Qty: 1 bottle (30 tablets/bottle), then 11 refills,

or _____ refills

For **1-mg** maintenance dose patients:

MAYZENT (siponimod) tablets

0.25-mg tablet - Starter Pack.....NDC 0078-0979-89

1-mg tablet, Bottle of 30 tablets.....NDC 0078-1014-15

1-mg Starter Pack:

No, patient already on therapy

Yes, 0.25-mg Starter Pack

SIG: seven 0.25-mg tablets for a 4-day supply

Day 1: 1 x 0.25 mg

Day 2: 1 x 0.25 mg

Day 3: 2 x 0.25 mg

Day 4: 3 x 0.25 mg

Qty: 1 Starter Pack, then 1 refill

Maintenance Dose:

1-mg tablet

SIG: 1-mg tablet taken orally once a day

Qty: 1 bottle (30 tablets/bottle), then 11 refills,

or _____ refills

Free Drug Access Program Prescription: (optional for Bridge to Commercial Coverage,⁸ Temporary Supply, or NPAF patients)

Dispensed directly from Homescripts™ at no cost to the patient (check only 1 box):

For **2-mg** maintenance dose patients:

Starter Pack:

No, patient already on therapy

Yes, 0.25-mg Starter Pack

SIG: twelve 0.25-mg tablets for a 5-day supply

Day 1: 1 x 0.25 mg **Day 4:** 3 x 0.25 mg

Day 2: 1 x 0.25 mg **Day 5:** 5 x 0.25 mg

Day 3: 2 x 0.25 mg

Qty: 1 Starter Pack, then 1 refill

Maintenance Dose:

2-mg tablet

SIG: 1 tablet taken orally once a day

Qty: 1 bottle (30 tablets/bottle), then 11 refills,

or _____ refills

For **1-mg** maintenance dose patients:

Starter Pack:

No, patient already on therapy

Yes, 0.25-mg Starter Pack

SIG: seven 0.25-mg tablets for a 4-day supply

Day 1: 1 x 0.25 mg

Day 2: 1 x 0.25 mg

Day 3: 2 x 0.25 mg

Day 4: 3 x 0.25 mg

Qty: 1 Starter Pack, then 1 refill

Maintenance Dose:

1-mg tablet

SIG: 1-mg tablet taken orally once a day

Qty: 1 bottle (30 tablets/bottle), then 11 refills,

or _____ refills

6. SIGNATURE AND PHYSICIAN ATTESTATION

Cannot process form without this field completed

You must authorize these instructions by signing at the end of this section. We cannot process this form without your signature.

I certify the above therapy is medically necessary and this information is accurate to the best of my knowledge. I certify I am the physician who has prescribed MAYZENT to the previously identified patient. I have discussed the Alongside program with my patient, who has authorized me under HIPAA and state law to disclose their information to Novartis for the limited purpose of enrolling in the Alongside program. To complete this enrollment, Novartis may contact the patient by phone, text and/or email. For the purposes of transmitting these prescriptions, I authorize NPAF, Novartis Pharmaceuticals Corporation, and its affiliates, business partners, and agents to forward as my agent for these limited purposes these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies. I will not attempt to seek reimbursement for free product provided to me for purposes of performing a first-dose observation. I have read and agree to the Prescriber Authorization for the NPAF on page 4.

→ X

Prescriber Signature (Dispense as Written)

(Substitution Permissible)

Date of Signature (MM/DD/YYYY)

ATTN: New York and Iowa prescribers, please submit electronic prescription to Homescripts Pharmacy, NPI#1528362076.

⁸A CYP2C9 genotype blood test that is processed through Labcorp is available at no cost. The cost of the genotype blood test may not be billed to any third-party payer. If your HCP does not submit for reimbursement of this test, commercially insured patients can submit a Medical Claim Reimbursement Request Form to IQVIA to get reimbursed for initial assessments and FDO for up to \$900, after a [\$125] deductible. Limitations may apply. Offer not valid for services (i) performed in RI, (ii) for which payment may be made in whole or in part under federal or state health care programs, including, but not limited to, Medicare or Medicaid, or (iii) where prohibited by law. There is a cash-pay option for residents of RI. No purchase required. Program subject to termination at any time. For questions regarding covered services, please contact your Alongside Coordinator.

⁹An ophthalmic evaluation of the fundus, including the macula, is recommended in all patients before starting treatment.

¹⁰FDO is recommended for patients with certain preexisting cardiac conditions, including sinus bradycardia, first- or second-degree [Mobitz type I] AV block, or a history of myocardial infarction or heart failure.

¹¹For patients with a CYP2C9*1*3 or *2*3 genotype, the recommended maintenance dose of MAYZENT is 1 mg once daily. For treatment initiation in these patients, the first month's supply should be used. MAYZENT should not be used in patients with a CYP2C9*3*3 genotype. An FDA-cleared or -approved test for the detection of CYP2C9 variants to direct the use of siponimod is not currently available.

¹²Eligible patients must have commercial insurance and a valid prescription for MAYZENT. By participating, patient acknowledges intent to pursue insurance coverage for MAYZENT with their health care provider. Program requires the submission of a request for coverage within 9 months post-Program initiation in order to remain eligible. Patients will receive their maintenance drug supply each month for up to 12 months or until they receive insurance coverage approval, whichever occurs earlier. Program is not available to patients who are uninsured or whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program, or where prohibited by law. Patients may be asked to reverify insurance coverage status during the course of the Program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Other limitations may apply. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

FAX BOTH PAGES TO 1-877-750-9068

Please read the following carefully, then check the box where indicated on the previous pages.

PATIENT AUTHORIZATION. I authorize my health care providers, pharmacies and health insurers, and their service providers (“Providers”) to disclose information relating to my insurance benefits, medical condition, treatment, **genetic information, including the results of genetic testing** and prescription details (“Personal Information”) to Novartis Pharmaceuticals Corporation, its affiliates and service providers (“Novartis”) and the Novartis Patient Assistance Foundation, Inc., and its service providers (“NPAF”) so they can provide the following support services (the “Services”):

- Help coordinate insurance coverage for, access to, and receipt of my medication.
- Communicate with me about possible financial assistance, including Novartis copay or NPAF programs, and, if I am enrolled, administer my participation in those programs.
- Communicate with me about my medication and treatment, including reminders, health and lifestyle tips, and product and other related information. Communications may be customized based on Personal Information obtained from my Providers.
- Conduct quality assurance and other internal business activities and ask for feedback related to the Services or my treatment.

In delivering the Services, Novartis and NPAF may share my Personal Information with each other, with my Providers, or with government agencies or other financial assistance programs that might help me pay for my medication. They may combine information collected from me with information collected from other sources and use that information to administer the Services. My pharmacies or other health care providers may receive payment from Novartis or NPAF for providing certain Services, such as medication or refill reminders, based on my enrollment or participation. Once I authorize disclosure of my Personal Information, it may no longer be protected by federal health privacy law and applicable state laws.

I understand I do not have to sign this Authorization to get my medication or insurance coverage, that I have a right to a copy, and can cancel this Authorization at any time by calling 1-877-629-9368 or writing to:

PO Box 2971

850 Twin Rivers Dr

Columbus, OH 43216-9532

OR

Customer Interaction Center

Novartis Pharmaceuticals Corporation, One Health Plaza

East Hanover, NJ 07936-1080

This Authorization will expire 5 years after I sign it, or earlier if required by state law, unless I cancel it sooner. If I cancel it, I may no longer qualify for Services from Novartis or NPAF, but it will not impact my Provider’s treatment or my insurance benefits. I also understand that if a Provider is disclosing my Personal Information to Novartis or NPAF on an authorized, ongoing basis, my cancellation will be effective with respect to that provider as soon as they receive notice of my cancellation. Cancellation will not affect prior uses or disclosures.

Telephone Consumer Protection Act (TCPA) Consent

I consent to receive marketing calls and texts from and on behalf of the Novartis Group and NPAF, made with an auto-dialer or prerecorded voice, at the phone number(s) provided. I understand that my consent is not required or a condition of purchase. Number of messages will vary based on your Program selections. Message and data rates may apply. I understand that I can read the full Novartis Pharmaceuticals Corporation Privacy Policy at www.usprivacy.novartis.com. Text STOP to opt out and HELP for help.

MAYZENT Co-pay Program Terms and Conditions

Limitations apply. Valid only for those with private insurance. The Program includes the Co-Pay Card, Payment Card (if applicable), and Rebate, with a combined annual limit of \$18,000. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, or (iii) where the patient’s insurance plan reimburses for the entire cost of the drug. The value of this Program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this Program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

Fair Credit Reporting Act (FCRA) Authorization

I understand that I am providing “written instructions” authorizing NPAF and its vendor, under the FCRA, to obtain information from my credit profile or other information from the vendor, solely for the purpose of determining financial qualifications for programs administered by NPAF. I understand that I must affirmatively agree to these terms in order to proceed in this financial screening process.

Prescriber Authorization for the Novartis Patient Assistance Foundation, Inc. (NPAF)

I certify that any medication received will be used only for the patient named on this form and will not be offered for sale, trade, or barter. Furthermore, no claim for reimbursement will be submitted concerning this medication, nor will any medication be returned for credit. I acknowledge that NPAF is exclusively for purposes of patient care and not for remuneration of any sort. I understand that NPAF may revise, change, or terminate programs at any time.

INDICATION

MAYZENT® (siponimod) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

Contraindications

- Patients with a CYP2C9*3/*3 genotype
- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- Presence of Mobitz type II second-degree, third-degree atrioventricular block, or sick sinus syndrome, unless patient has a functioning pacemaker

Infections: MAYZENT may increase risk of infections with some that are serious in nature. Life-threatening and rare fatal infections have occurred.

Before starting MAYZENT, review a recent complete blood count (CBC) (ie, within 6 months or after discontinuation of prior therapy). Delay initiation of treatment in patients with severe active infections until resolved. Employ effective treatments and monitor patients with symptoms of infection while on therapy. Consider discontinuing treatment if patient develops a serious infection.

Cases of fatal cryptococcal meningitis (CM) were reported in patients treated with another sphingosine 1-phosphate (S1P) receptor modulator. Rare cases of CM have occurred with MAYZENT. If CM is suspected, MAYZENT should be suspended until cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated.

Cases of herpes viral infection, including cases of meningitis or meningoencephalitis caused by VZV reactivation, have been reported. Patients without a confirmed history of varicella zoster virus (VZV) or without vaccination should be tested for antibodies before starting MAYZENT. If VZV antibodies are not present or detected, then VZV immunization is recommended and MAYZENT should be initiated 4 weeks after vaccination.

Use of live vaccines should be avoided while taking MAYZENT and for 4 weeks after stopping treatment.

Caution should be used when combining treatment (ie, anti-neoplastic, immune-modulating, or immunosuppressive therapies) due to additive immune system effects.

Progressive Multifocal Leukoencephalopathy (PML): Cases of PML have occurred in patients with MS treated with S1P receptor modulators, including MAYZENT. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. PML has occurred in MAYZENT-treated patients who had not been treated previously with natalizumab (which has a known association with PML), were not taking any other immunosuppressive or immunomodulatory medications concomitantly, and did not have any ongoing systemic medical conditions resulting in compromised immune system function. The majority of cases of PML associated with S1P receptor modulators, including MAYZENT, have occurred in patients treated for at least 2 years. The relationship between the risk of PML and the duration of treatment is unknown.

At the first sign or symptom suggestive of PML, withhold MAYZENT and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. MRI findings may be apparent before clinical signs or symptoms. Cases of PML, diagnosed based on MRI findings and the detection of JCV DNA in the cerebrospinal fluid in the absence of clinical signs or symptoms specific to PML, have been reported in patients treated with MS medications associated with PML, including S1P receptor modulators. Many of these patients subsequently became symptomatic with PML. Therefore, monitoring with MRI for signs that may be consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present. Lower PML-related mortality and morbidity have been reported following discontinuation of another MS medication associated with PML in patients with PML who were initially asymptomatic compared to patients with PML who had characteristic clinical signs and symptoms at diagnosis. It is not known whether these differences are due to early detection and discontinuation of MS treatment or due to differences in disease in these patients.

If PML is confirmed, treatment with MAYZENT should be discontinued. Immune reconstitution inflammatory syndrome (IRIS) has been reported in patients treated with S1P receptor modulators, including MAYZENT, who developed PML and subsequently discontinued treatment. IRIS presents as a clinical decline in the patient's condition that may be rapid, can lead to serious neurological complications or death, and is often associated with characteristic changes on MRI. The time to onset of IRIS in patients with PML was generally within a few months after S1P receptor modulator discontinuation. Monitoring for development of IRIS and appropriate treatment of the associated inflammation should be undertaken.

Macular Edema: In most cases, macular edema occurred within 4 months of therapy. Patients with history of uveitis or diabetes are at an increased risk. Before starting treatment, an ophthalmic evaluation of the fundus, including the macula, is recommended and at any time if there is a change in vision. The use of MAYZENT in patients with macular edema has not been evaluated; the potential risks and benefits to the individual patient should be considered.

Bradycardia and Atrioventricular Conduction Delays: Prior to initiation of MAYZENT, an ECG should be obtained to determine if preexisting cardiac conduction abnormalities are present. In all patients, a dose titration is recommended for initiation of MAYZENT treatment to help reduce cardiac effects.

MAYZENT was not studied in patients who had:

- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, or decompensated heart failure requiring hospitalization
- New York Heart Association Class II-IV heart failure
- Cardiac conduction or rhythm disorders, including complete left bundle branch block, sinus arrest or sino-atrial block, symptomatic bradycardia, sick sinus syndrome, Mobitz type II second-degree AV-block or higher-grade AV-block (either history or observed at screening), unless patient has a functioning pacemaker
- Significant QT prolongation (QTc greater than 500 msec)
- Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic drugs

Reinitiation of treatment (initial dose titration, monitoring effects on heart rate and AV conduction [ie, ECG]) should apply if ≥4 consecutive daily doses are missed.

Respiratory Effects: MAYZENT may cause a decline in pulmonary function. Spirometric evaluation of respiratory function should be performed during therapy if clinically warranted.

Liver Injury: Elevation of transaminases may occur in patients taking MAYZENT. Before starting treatment, obtain liver transaminase and bilirubin levels. Closely monitor patients with severe hepatic impairment. Patients who develop symptoms suggestive of hepatic dysfunction should have liver enzymes checked, and MAYZENT should be discontinued if significant liver injury is confirmed.

Cutaneous Malignancies: The risk of cutaneous malignancies (including basal cell carcinoma (BCC), squamous cell carcinoma (SCC), and melanoma) is increased in patients treated with S1P modulators. Use of MAYZENT has been associated with an increased risk of BCC and SCC. Cases of other cutaneous malignancies, including melanoma, have also been reported in patients treated with MAYZENT and in patients treated with another S1P modulator.

Skin examinations are recommended at the start of treatment and periodically thereafter for all patients. Monitor for suspicious skin lesions and promptly evaluate any that are observed. Exposure to sunlight and ultraviolet light should be limited by wearing protective clothing and using a sunscreen with high protection factor. Concomitant phototherapy with UV-B radiation or PUVA-photochemotherapy is not recommended.

Increased Blood Pressure: Increase in systolic and diastolic pressure was observed about 1 month after initiation of treatment and persisted with continued treatment. During therapy, blood pressure should be monitored and managed appropriately.

Fetal Risk: Based on animal studies, MAYZENT may cause fetal harm. Women of childbearing potential should use effective contraception to avoid pregnancy during and for 10 days after stopping MAYZENT therapy. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to MAYZENT during pregnancy. Healthcare providers are encouraged to enroll pregnant patients, or pregnant women may register themselves in the MotherToBaby Pregnancy Study in Multiple Sclerosis by calling 1-877-311-8972, sending an email to MotherToBaby@health.ucsd.edu, or visiting www.mothertobaby.org/join-study.

Posterior Reversible Encephalopathy Syndrome (PRES): Rare cases of PRES have been reported in patients receiving an S1P receptor modulator. Such events have not been reported for patients treated with MAYZENT in clinical trials. If patients develop any unexpected neurological or psychiatric symptoms, a prompt evaluation should be considered. If PRES is suspected, MAYZENT should be discontinued.

Unintended Additive Immunosuppressive Effects From Prior Treatment or After Stopping MAYZENT: When switching from drugs with prolonged immune effects, the half-life and mode of action of these drugs must be considered to avoid unintended additive immunosuppressive effects.

Initiating treatment with MAYZENT after treatment with alemtuzumab is not recommended.

After stopping MAYZENT therapy, siponimod remains in the blood for up to 10 days. Starting other therapies during this interval will result in concomitant exposure to siponimod.

Lymphocyte counts returned to the normal range in 90% of patients within 10 days of stopping therapy. However, residual pharmacodynamic effects, such as lowering effects on peripheral lymphocyte count, may persist for up to 3-4 weeks after the last dose. Use of immunosuppressants within this period may lead to an additive effect on the immune system, and therefore, caution should be applied 3-4 weeks after the last dose of MAYZENT.

Severe Increase in Disability After Stopping MAYZENT: Severe exacerbation of disease, including disease rebound, has been rarely reported after discontinuation of an S1P receptor modulator. The possibility of severe exacerbation of disease should be considered after stopping MAYZENT treatment, thus patients should be monitored upon discontinuation.

After stopping MAYZENT in the setting of PML, monitor for development of immune reconstitution inflammatory syndrome (PML-IRIS).

Most Common Adverse Reactions: Most common adverse reactions (>10%) are headache, hypertension, and transaminase increases.

Please see accompanying full [Prescribing Information](#), including Medication Guide.

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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11/23

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